参考資料7

PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)

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INTRODUCTION

Diseases caused by foodborne microbial hazards[1] constitute a world-wide public health concern. During the past several decades, the incidence of foodborne diseases has increased in many parts of the world. Foodborne threats occur for a number of reasons. These include microbial adaptation, changes in the food production systems, including new feeding practices, changes in animal husbandry, agronomic process and food technology, increase in international trade, susceptible populations and travel, change in lifestyle and consumers demands, changes in human demographics and behaviour. The globalisation of food markets has increased the challenge to manage these risks.

Effective management of risks arising from microbial hazards is technically complex. Food safety has been traditionally, and will continue to be, the responsibility of industry operating an array of control measures relating to the food hygiene within an overall regulatory framework. Recently, risk analysis, involving its component parts of risk assessment, risk management and risk communication, has been introduced as a new approach in evaluating and controlling microbial hazards to help protecting the health of consumers and ensure fair practices in food trade. It could also facilitate the judgement of equivalence of food safety control systems.

This document should be read in close conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[2] and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30 – 1999). Countries, organisations and individuals involved with MRM are encouraged to utilise these guidelines in concert with technical information developed by the World Health Organisation, the Food and Agriculture Organisation and the Codex Alimentarius (e.g. FAO/WHO Expert Consultation on Risk Management and Food Safety-Paper N°65, Rome 1997, WHO Expert Consultation - The Interaction between Assessors and Managers of Microbial Hazards in Food, Kiel, Germany, March 2000 - The Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts, Report Kiel, Germany, March 2002 – The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to improve food safety, Kiel, Germany, April 2006.

1. SCOPE

These principles and guidelines provide a framework for the MRM process and are intended for use by Codex and countries[3], as appropriate. They also provide guidance on the application of microbiological risk assessment (MRA) within the MRM process. Where specific recommendations apply only to Codex, or only to countries, this is so noted in the text. This document also provides useful guidance for other interested parties in implementing risk management options, such as industry[4] and consumers who are involved in MRM on a day-to-day basis.

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1 Foodborne microbial hazards include (but are not limited to) pathogenic bacteria, viruses, algae, protozoa, fungi, parasites, prions, toxins and other harmful metabolites of microbial origin.

2 See Codex Alimentarius Commission, *Procedural Manual.*

3 For the purpose of this document, each time the terms "country", "government", "national" are used, the provision applies both to Codex Members and Codex Member Organisations , i. e. regional economic integration organisation (REIO) – see Codex Alimentarius Commission, Procedural Manual

4 For the purpose of this document, it is understood that industry includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius).

2. DEFINITIONS

The definitions of risk analysis terms related to food safety incorporated in the Procedural Manual of the CAC[5], shall apply. See definitions of **hazard, risk, risk analysis, risk assessment, hazard identification, hazard characterisation, dose-response assessment, exposure assessment, risk characterisation, risk management, risk communication, risk assessment policy, risk profile, risk estimate, food safety objective (FSO), performance objective (PO), performance criterion (PC), traceability/product tracing and equivalence.**

The definitions from *The Guidelines for the Application of the HACCP System*[6], e.g. **control measure, step** or **critical control point**, the definition of a **microbiological criterion** included in *The Principles for the Application of Microbiological Criteria for Food (CAC/GL 21-1997)* and the definition of **interested parties** included in *The Working Principles for Risk Analysis for Application in the Framework of the Codex*[7] shall apply too.

The definition of the appropriate level of protection (**ALOP**) is the one included in the WTO Agreement on the Application of sanitary and phytosanitary measures (SPS agreement), Annex A, para 5.

The definitions of **validation, verification** and **food safety control system** are under development in the draft *Guidelines for the Validation of Food Safety Control Measures.*

Risk manager[8] is defined as follows: a national or international governmental organisation with responsibility for MRM.

3. GENERAL PRINCIPLES FOR MRM

•PRINCIPLE 1: Protection of human health is the primary objective in MRM.
•PRINCIPLE 2: MRM should take into account the whole food chain.
•PRINCIPLE 3: MRM should follow a structured approach.
•PRINCIPLE 4: MRM process should be transparent, consistent and fully documented.
•PRINCIPLE 5: Risk managers should ensure effective consultations with relevant interested parties.
•PRINCIPLE 6: Risk managers should ensure effective interaction with risk assessors.
•PRINCIPLE 7: Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options.
•PRINCIPLE 8: MRM decisions should be subject to monitoring and review and, if necessary, revision.

4. GENERAL CONSIDERATIONS

Codex and government decisions and recommendations have as their primary objective the protection of the health of consumers. Decision making should be timely to achieve that objective. In the MRM process, the ALOP is a key concept, as it is a reflection of a particular country's expressed public health goals for foodborne risks.

MRM should address the food chains as individual continuums, when considering means for controlling the public health risks associated with food. This should typically include primary production (including feeds, agricultural practices, and environmental conditions leading to the contamination of crops and animals), product design and processing, transport, storage, distribution, marketing, preparation, and consumption. This should include both domestic and imported products to the extent feasible.

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5 Codex Alimentarius Commission, Procedural Manual.

6 Annex to CAC/RCP 1-1969.

7 Codex Alimentarius Commission, Procedural Manual.

8 The definition of Risk Manager is derived from the definition for risk management which does not include all of the individuals who are involved in the implementation phase and related activities associated with MRM, i.e., MRM decisions are largely implemented by industry and other interested parties. The focus of the definition on risk manager is restricted to governmental organizations with authority to decide on the acceptability of risk levels associated to foodborne hazards.

MRM should follow a structured approach that includes preliminary MRM activities, identification and selection of MRM options, implementation of MRM activities, and monitoring and review of the options taken.

In order to facilitate a broader understanding by interested parties, MRM process should be transparent and fully documented. Risk managers should articulate and implement uniform procedures and practices to be used in the development and implementation of MRM, the determination of MRA policy, establishment of MRM priorities, allocation of resources (e.g. human, financial, time) and determination of the factors[9] to be used in the evaluation of MRM options. They should ensure that the options selected protect the health of consumers, are scientifically justifiable, proportionate to the risk identified and are not more restrictive of trade or technological innovation than required to achieve the ALOP. Risk managers should ensure that decisions are practicable and effective, and where appropriate, enforceable.

Risk managers should ensure effective and timely consultation with all relevant interested parties and provide a sound basis for understanding the MRM decision, its rationale and implications. The extent and nature of public consultation will depend on the urgency, complexity and uncertainties related to the risk and the management strategies being considered. Decisions and recommendations on MRM should be documented, and where appropriate clearly identified in Codex or national standards and regulations, so as to facilitate a wider understanding of the conduct of MRM.

The mandate given by risk managers to risk assessors relating to the conduct of an MRA should be as clear as possible. Interaction should allow risk managers to be informed by risk assessors of any constraints, data gaps, uncertainties, assumptions and their impact on the MRA. Where there is disagreement among the risk assessors, the risk managers should be informed of the minority opinions and these differences should be documented.

MRM decisions regarding foodborne hazards will vary according to the regional microbial conditions. MRM should take into account the diversity of production methods and processes, inspection, monitoring and verifications systems, sampling and testing methods, distribution and marketing systems, consumer food use patterns, consumers' perception and the prevalence of specific adverse health effect.

MRM should be an iterative process and decisions made should be subject to timely review, taking into account all relevant newly generated data, with a goal toward further risk reduction and public health improvement.

5. PRELIMINARY MICROBIOLOGICAL RISK MANAGEMENT ACTIVITIES

5.1 IDENTIFICATION OF A MICROBIOLOGICAL FOOD SAFETY ISSUE

A food safety issue arises where one or more foodborne microbial hazard(s) are known or thought to be associated with one or many food(s) and thus requires consideration of a risk manager. The risk manager follows the MRM process to evaluate and where necessary manage the associated risk. At the start of this process, the food safety issue should be clearly identified and communicated from the risk managers to risk assessors, as well as affected consumers and industry.

Food safety issue identification may be performed by the risk manager or be the result of collaboration between different interested parties. Within Codex, a food safety issue may be raised by a member government, or by an intergovernmental or observer organisation.

Food safety issues may be identified on the basis of information arising from a variety of sources, such as surveys of the prevalence and concentration of hazards in the food chain or the environment, human disease surveillance data, epidemiological or clinical studies, laboratory studies, scientific, technological or medical advances, lack of compliance with standards, recommendations of experts, public input, etc.

[9] See Codex Alimentarius Commission, Procedural Manual.

Some food safety issues may require that an immediate action[10] be taken by the risk manager without further scientific consideration (e.g. requiring withdrawal / recall of contaminated products). Countries will often not be able to delay taking an immediate action when there is an imminent public health concern demanding an urgent response. Such measures should be temporary, clearly communicated as well as subject to review within a time frame.

When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and, if necessary, modify the provisional decision. In those instances, the provisional nature of the decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after the completion of a MRA) should be articulated when the decision is communicated initially).

5.2 MICROBIOLOGICAL RISK PROFILE

The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential MRM options that have been identified to date, when any, and the food safety policy context that will influence further possible actions. The **Annex** provides information about suggested risk profile elements for guidance to risk managers at the national level, and for bringing forward newly proposed work within CCFH.

Consideration of the information given in the risk profile may result in a range of initial decisions, such as commissioning an MRA, gathering more information or developing risk knowledge at the level of the risk manager, implementing an immediate and/or temporary decision (see section 5.1 above). National governments may also base their MRM decisions on Codex standards, recommendations and guidance where available. In some cases, the risk profile could give enough information for identification and selection of MRM options. In other cases, no further action may be needed.
The risk profile provides an initial analysis that describes possible MRM options. The MRM options can take the form of a draft MRM guidance document that will be introduced into the Codex step process (e.g., codes of practice, guidance documents, microbiological specifications, etc.).

5.3 RISK ASSESSMENT POLICY

Refer to the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius[11]. National governments should establish a MRA policy relevant to their circumstances, in advance of the microbiological risk assessment.

Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors. Establishing a risk assessment policy protects the scientific integrity of the risk assessment and offers guidance to balance value judgements, policy choices, adverse health parameters for presenting risk to human health, source of data to be considered, and management of data gaps and uncertainties during the course of the assessment. The risk assessment policy could be of a generic nature or MRA-specific, and should be documented to ensure consistency, clarity and transparency.

5.4 MICROBIOLOGICAL RISK ASSESSMENT

Risk managers may commission an MRA to provide an objective, systematic evaluation of relevant scientific knowledge to help make an informed decision.

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[10] The International Health Regulation (2005) Agreement gives provisions for appropriate measures in case of public health emergencies, including food related events (www.who.int/csr/ihr/ihrwha58_3-en.pdf). The Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situation (CAC/GL 19-1995) defines a **food safety emergency** as a situation whether accidental or intentional that is identified by a competent authority as constitutes a serious and as yet uncontrolled foodborne risk to public health that requires urgent action. Emergency measures may be part of immediate action.

[11] See Codex Alimentarius Commission, Procedural Manual.

The risk manager should refer to the *Principles and Guidelines for the Conduct of MRA* (CAC/GL-30 (1999). It is important to ensure that a clear mandate is given to risk assessors and that the MRA meets the needs of the risk manager. It is also important that the MRA be adequately reviewed by the scientific community and if appropriate, the public.

The outputs of the MRA should be presented by risk assessors in such a manner that they can be properly understood and utilised by risk managers in the evaluation of the suitability of different MRM options to manage the food safety issue. Generally, the presentation is conveyed in two different formats: a fully detailed technical report and an interpretative summary for a broader audience.

For the best use of an MRA, risk managers should be fully informed of the strengths and limitations (key assumptions, key data gaps, uncertainty and variability in the data, and their influences on the outcomes), including a pragmatic appreciation of uncertainties associated to the MRA study and its outputs. Risk managers, in consultation with risk assessors, should then decide whether the MRA is in developing and/or evaluating and deciding on suitable MRM activities, or deciding on provisional MRM options.

6. IDENTIFICATION AND SELECTION OF MRM OPTIONS

6.1 IDENTIFICATION OF THE AVAILABLE MRM OPTIONS FOR CODEX AND COUNTRIES

The risk manager needs to ensure that MRM options are identified and the acceptable one(s) selected for subsequent implementation by relevant interested parties. In this, risk managers need to consider the suitability of MRM options to reduce the risk posed by a food safety issue to an appropriate level and any practical issues regarding the implementation of the selected MRM options that need to be managed.

Examples of potential MRM options (used either alone or in combination) available for Codex or countries, as appropriate are listed below.

6.1.1 Codex

- elaboration of standards and related texts[12];

6.1.2 Countries

- establish regulatory requirements;
- develop (or encourage the development of) specific documents and guides e.g. Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), HACCP;
- adopt or adapt Codex standards and related texts to the national situation;
- define an FSO for a particular food safety issue, leaving flexibility to industry to select appropriate control measures to meet it;
- establish control measures specifying relevant requirements for industry that do not have the means to establish appropriate measures themselves or who adopt such control measures, including as appropriate metrics[13] at specific stages of the food/feed[14] chain where they are of critical importance to the performance of the overall chain;

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[12] When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as code of practice, provided that susch a text would supported by the available scientific evidence, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, Codex Alimentarius Commission, Procedural Manual, 16 Edition.

[13] See the Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts, Report of Kiel, Germany, March 2002.

[14] In those instances where the presence of hazards in feed may affect the safety of foods derived from an animal, the microbiological profile of feed should be considered.

- establish requirements for inspection and audit procedures, certification or approval procedures;
- require import certificates for certain products;
- promulgate awareness and develop educational and training programs to communicate that:
  - prevention of contamination and/or introduction of hazards should be addressed at all relevant stages in the food/feed chain;
  - rapid withdrawal/recall of food/feed procedures are in place, including appropriate traceability/product tracing for effectiveness;
  - properly labelling includes information that instructs the consumer regarding safe handling practices and, where appropriate, briefly informs the consumer of the food safety issue;

6.2 SELECTION OF MRM OPTIONS

The selection of MRM options should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options. Where available, an MRA can often help in the evaluation and selection of MRM options.

The selection of MRM options that are both effective and feasible should generally include consideration of the following:

- planned control of hazards (e.g. with HACCP) is more effective than detecting and correcting food safety control system failures (e.g., lot-release microbiological testing of finished products);
- the population may be exposed to multiple potential sources of a particular hazard;
- the suitability of the option to be monitored, reviewed and revised during subsequent implementation;
- the capacity of the food businesses to manage food safety (e.g. human resources, size, type of operation). For instance, a more traditional approach may be selected for small and less developed food businesses, rather than an FSO driven approach

6.2.1 Responsibility for selecting MRM options

The primary responsibility for selecting appropriate MRM options lies with the risk manager.
Risk assessors and other interested parties play an important role in this process by providing information that permits the evaluation and, if appropriate, comparison of different MRM options.

Whenever feasible, both Codex and countries should attempt to specify the level of control or risk reduction that is necessary (i.e. establish the stringency required for food safety control systems), while providing to the extent feasible some flexibility in options that the industry can use to achieve the appropriate level of control.

6.2.2 MRM options based on risk

The increasing adoption of risk analysis is allowing more transparent approaches for relating ALOP to the required stringency of the food safety control system, and for the comparison of MRM options for their suitability and, possibly, equivalence. This has allowed the use of traditional MRM options as well as the development of new MRM tools, e.g. FSO, PO and PC and the enhancement of the scientific basis of existing MRM tools, e.g. microbiological criteria (MC).

7. IMPLEMENTATION OF MRM OPTIONS

Implementation involves giving effect to the selected MRM option(s) and verifying compliance, i.e. assuring that the MRM option(s) is/are implemented as intended. Implementation may involve different interested parties, including competent authorities, industry and consumers. Codex does not implement MRM options.

7.1 INTERNATIONAL INTERGOVERNMENTAL ORGANISATIONS

Developing countries may need specific assistance in developing and selecting implementation strategies as well as in the area of education. Such assistance should be provided by international intergovernmental organisations, e.g. FAO and WHO, and developed countries in the spirit of the SPS Agreement.

7.2 COUNTRIES

The implementation strategy will depend on the MRM option(s) selected and should be developed within a consultative process with interested parties. Implementation can occur at different points in the food/feed chain and may involve more than one segment of the industry and consumers.

Once an MRM option is selected, risk managers should develop an implementation plan that describes how the option will be implemented, by whom, and when. In some situations, a stepwise phase-in implementation strategy could be considered, e.g. different sized establishments or different sectors, in part based on risk and/or capability. Guidance and support may need to be provided in particular for small and less developed businesses.

To ensure transparency, risk managers should communicate decisions on MRM options to all interested parties, including the rationale, and how those affected will be expected to implement. To the extent imports will be affected, other governments should be informed of the decision(s) and rationale in order to ensure their own MRM strategies to achieve equivalence.
If the MRM options selected are provisional, the rationale and the expected timeframe for finalising the decision should be communicated.

Governments should ensure an appropriate regulatory framework and infrastructure, including adequately trained personnel and inspection staff, in order to enforce regulations and verify compliance. Inspection and targeted sampling plans may be applied at different steps of the food chain. The competent authorities should ensure that industry applies the appropriate good practices and, within the application of the HACCP system, does effectively monitor CCPs and implement corrective actions and verification steps.

Governments should define an evaluation process to assess whether the MRM options have been properly implemented. This process should allow for adjustment of the implementation plan or of the MRM options, if the options selected are not successful in achieving the required level of control over the hazard. This is intended to provide short-term evaluation to allow modification, particularly for provisional MRM options, versus longer-term monitoring and review, as discussed in 8.1 and 8.2.

7.3 INDUSTRY

Industry is responsible for developing and applying food safety control systems to give effect to the decisions on MRM options. Depending on the nature of the MRM option, this may require activities such as:

- Establishing metrics that will achieve or contribute to established FSOs or other regulatory requirements;
- The identification of PC and design and implementation of appropriate combinations of validated control measures;
- Monitoring and verification of the food safety control system or relevant parts thereof (e.g. control measures, good practices)
- Application, as appropriate, of sampling plans for microbiological analyses;

- Development of plans for corrective actions, that may include withdrawal/recall procedures, traceability/product tracing etc;
- Effective communication with suppliers, customers and/or consumers, as appropriate;
- Training or instruction of staff and internal communication.

Industry associations may find it beneficial to develop and provide guidance documents, training programs, technical bulletins and other information that assists industry to implement control measures.

7.4 CONSUMER

Consumers can enhance both their personal and the public's health by being responsible for, adhering to, being informed of and following food safety-related instructions. Multiple means of providing this information to consumers should be undertaken, such as public education programs, appropriate labelling, and public interest messages. Consumer organisations can play a significant role in getting this information to consumers.

8. MONITORING AND REVIEW

8.1 MONITORING

An essential part of the MRM process is the on-going gathering, analysing, and interpreting of data related to the performance of food safety control systems, which, in this context is referred to as monitoring. Monitoring is essential to establish a baseline for comparing the effectiveness of new MRM activities. It also may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the extent or efficiency of risk mitigation and public health. Risk management programs should strive for continual improvement in public health.
Monitoring activities related to measuring the state of public health are in most cases the responsibility of national governments. For instance, surveillance of human populations and the analysis of human health data on a national level are generally conducted by countries. International organisations such as WHO provide guidance for establishing and implementing public health monitoring programs.

Monitoring activities respecting microbial hazards may be needed at multiple points along the entire food chain to identify food safety issues and to assess public health and food safety status and trends. Monitoring should provide information on all aspects of risks from specific hazards and foods relevant to MRM, and is key to the generation of data for the development of a risk profile or an MRA as well as for the review of MRM activities. Monitoring should also include evaluating the effectiveness of consumer communication strategies.

Monitoring activities can include the collection and analysis of data derived from:

- surveillance of clinical diseases in humans, as well as diseases in plants and animals that can affect humans;
- epidemiological investigations of outbreaks and other special studies;
- surveillance based on laboratory tests of pathogens isolated from humans, plants, animals, foods, and food processing environments for pertinent foodborne hazards;
- data on environmental hygiene practices and procedures;
- behavioural risk factor surveillance of food worker and consumer habits and practices.

When establishing or re-designing monitoring systems in countries, the following aspects should be considered:

- A public health surveillance system should be able to estimate the proportion of illnesses and death that is truly foodborne and the major food vehicles, processes, and food handling practices responsible for each hazard;

- Interdisciplinary teams of epidemiologists and food safety experts should be formed to investigate foodborne illness to identify the food vehicles and the series of events that lead to illnesses;
- Microbiological and/or physicochemical indicators of a particular intervention should be considered together with human disease data to evaluate programmatic impact on public health;
- Countries should work towards harmonisation of surveillance definitions and reporting rules, protocols, and data management systems, to facilitate comparison between countries of incidence and trends of the illnesses and microbiological data in the food chain.

8.2 REVIEW OF MRM ACTIVITIES

The effectiveness and appropriateness of the MRM activities selected, and of the implementation thereof, need to be reviewed. Review is an integral part of the MRM process and ideally should take place at a predetermined moment in time or whenever relevant information becomes available. Criteria for review should be established as part of the implementation plan. Review may lead to a change in the MRM activities

Planning periodic review of MRM activities is the best way to assess whether or not the expected consumer health protection is delivered. On the basis of a review of the information collected through the various appropriate monitoring activities, a decision may be taken to amend the MRM activities implemented or to substitute the option for another one.

MRM activities should be reviewed when new activities or new information (e.g., emerging hazard, virulence of a pathogen, prevalence and concentration in foods, sensitivity of sub-populations, changes in dietary intake patterns) become available.

Industry and other interested parties (e.g. consumers) can suggest the review of MRM options. Evaluation of the success of MRM activities in industry may include reviewing the effectiveness of the food safety control system and its pre-requisite programs, results of product testing, the incidence and nature of product withdrawals/recalls and consumer complaints.

The results of review and the associated actions that risk managers are considering to take, as a consequence of the review, should be made public and communicated to all interested parties.

ANNEX

SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK PROFILE

A risk profile should present, to the extent possible, information on the following.

1. Hazard-food commodity combination(s) of concern :
   - Hazard(s) of concern;
   - Description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this hazard have been associated;
   - Occurrence of the hazard in the food chain.
2. Description of the public health problem :
   - Description of the hazard including key attributes that are the focus of its public health impact (e.g., virulence characteristics, thermal resistance, antimicrobial resistance);
   - Characteristics of the disease, including;
     - Susceptible populations;
     - Annual incidence rate in humans including, if possible, any differences between age and sex;
     - Outcome of exposure;
     - Severity of clinical manifestations (e.g., case-fatality rate, rate of hospitalisation);
     - Nature and frequency of long-term complications;
     - Availability and nature of treatment;
     - Percentage of annual cases attributable to foodborne transmission.
   - Epidemiology of foodborne disease;
     - Aetiology of foodborne diseases;
     - Characteristics of the foods implicated;
     - Food use and handling that influences transmission of the hazard;
     - Frequency and characteristics of foodborne sporadic cases;
     - Epidemiological data from outbreak investigations;
   - Regional, seasonal, and ethnic differences in the incidence of foodborne illness due to the hazard;
   - Economic impact or burden of the disease if readily available;
     - Medical, hospital costs;
     - Working days lost due to illness, etc.
3. Food Production, processing, distribution and consumption :
   - Characteristics of the commodity (commodities) that are involved and that may impact on risk management;
   - Description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices);
   - What is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects;

- Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines);
- Identification of additional risk mitigation strategies that could be used to control the hazard.

4. Other Risk Profile Elements :
   - The extent of international trade of the food commodity;
   - Existence of regional/international trade agreements and how they may affect the public health impact with respect to the specific hazard/commodity combination(s);
   - Public perceptions of the problem and the risk;
   - Potential public health and economic consequences of establishing Codex MRM guidance document.
5. Risk Assessment Needs and Questions for the Risk Assessors :
   - Initial assessments of the need and benefits to be gained from requesting an MRA, and the feasibility that such an assessment could be accomplished within the required time frame;
   - If a risk assessment is identified as being needed, recommended questions that should be posed to the risk assessor;
6. Available Information and Major Knowledge Gaps Provide, to the extent possible, information on the following :
   - Existing national MRAs on the hazard/commodity combination(s) including, if possible;
   - Other relevant scientific knowledge and data that would facilitate MRM activities including, if warranted, the conduct of an MRA;
   - Existing Codex MRM guidance documents (including existing Codes of Hygienic Practice and/or Codes of Practice);
   - International and/or national governmental and/or industry codes of hygienic practice and related information (e.g., microbiological criteria) that could be considered in developing a Codex MRM guidance document;
   - Sources (organisations, individual) of information and scientific expertise that could be used in developing Codex MRM guidance document;
   - Areas where major absences of information exist that could hamper MRM activities including, if warranted, the conduct of an MRA