

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

CAC/GL 63-2007

## INTRODUCTION

Diseases caused by foodborne microbial hazards<sup>1</sup> 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<sup>2</sup> 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 Commission (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<sup>3</sup>, 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<sup>4</sup> and consumers who are involved in MRM on a day-to-day basis.

## 2. DEFINITIONS

The definitions of risk analysis terms related to food safety incorporated in the Procedural Manual of the CAC<sup>5</sup>, 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*<sup>6</sup>, e.g. **control measure, step or critical control point**, the definition of a **microbiological criterion** included in *The Principles and Guidelines for the Application of Microbiological Criteria Related to Foods (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*<sup>7</sup> shall apply too.

<sup>1</sup> 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.

<sup>2</sup> See Codex Alimentarius Commission, *Procedural Manual*.

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

<sup>4</sup> 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).

<sup>5</sup> Codex Alimentarius Commission, *Procedural Manual*.

<sup>6</sup> Annex to CAC/RCP 1-1969.

<sup>7</sup> Codex Alimentarius Commission, *Procedural Manual*.

The definition of the appropriate level of protection (**ALOP**) is the one in the WTO Agreement on the application of sanitary and phytosanitary measures (SPS agreement).

The definitions of **validation**, **verification** and **food safety control system** are those in the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008).

**Risk manager**<sup>8</sup> 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.

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<sup>9</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> See Codex Alimentarius Commission, *Procedural Manual*.

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.

Some food safety issues may require that an immediate action<sup>10</sup> 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 I** 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<sup>11</sup>. National governments should establish a MRA policy relevant to their circumstances, in advance of the microbiological risk assessment.

<sup>10</sup> 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](http://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.

<sup>11</sup> See Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission, *Procedural Manual*).

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.

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<sup>12</sup>;

##### 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<sup>13</sup> at specific stages of the food/feed<sup>14</sup> chain where they are of critical importance to the performance of the overall chain;
- establish requirements for inspection and audit procedures, certification or approval procedures;

<sup>12</sup> 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 a code of practice, provided that such a text would be 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*.

<sup>13</sup> 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.

<sup>14</sup> 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.

- 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 CONSUMERS**

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 I: 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

## ANNEX II: GUIDANCE ON MICROBIOLOGICAL RISK MANAGEMENT METRICS

### *Introduction*

Three general principles are articulated in the “General Principles of Food Hygiene,” its annex “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application,” and the recently adopted “Principles and Guidelines for the Conduct of Microbiological Risk Management:” (i) the stringency of food safety systems should be appropriate for the dual goals of managing risks to public health and ensuring fair practices in the food trade; (ii) the level of control required of a food safety control system should be based on risk and determined using a scientific and transparent approach; and (iii) the performance of a food safety control system should be verifiable. These goals have traditionally been achieved, in part, through the establishment of microbiological criteria (MC), process criteria (PcC), and/or product criteria (PdC). These metrics have provided both a means of articulating the level of stringency expected of a food safety control system and verifying that this level of control is being achieved. However, these traditional risk management tools have generally not been linked directly to a specific level of public health protection. Instead, these metrics have been based on qualitative consideration of the levels of hazards that are “as low as reasonably achievable,” a hazard-based approach that does not directly consider the level of control needed to manage a risk to public health. The recent adoption of the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” and the “Working Principles for Risk Analysis for Food Safety for Application by Governments” has emphasized the goal of Codex Alimentarius to develop risk-based approaches that can more directly and transparently relate the stringency of control measures to achievement of a specified level of public health protection.

A risk management approach based on risk is an important step in improving a food safety system based on science by linking food safety requirements and criteria to the public health problems they are designed to address. Recent advances in microbiological risk assessment (MRA) techniques, such as quantitative microbiological risk assessments (QMRA), qualitative risk assessments, and formalized expert elicitations, are increasingly making it possible to more systematically relate the performance of a control measure, a series of control measures or even an entire food safety control system to the level of control needed to manage a food safety risk. This has been particularly true with QMRA techniques which allow the impact of different degrees of stringency to be considered quantitatively in relation to predicted public health outcomes. This increased analytical capability has led to a series of new food safety risk management metrics, such as the Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC), which are intended to provide a bridge between traditional food safety metrics (i.e. MC, PcC, PdC) and the expected level of public health protection. Such metrics provide a potential means of articulating the level of stringency required of a food safety system at different points in the farm-to-table continuum, thereby providing a means for “operationalizing” the Appropriate Level of Protection (ALOP) concepts envisioned in the WTO SPS Agreement.

As outlined in the main body of this document, the ability to articulate the expected performance of control measures and food safety control systems in terms of the necessary management of public health risks is a critical component of the evolving Codex Alimentarius risk analysis paradigm. While MRA is increasingly used to evaluate the ability of control measures and food safety control systems to achieve a desired degree of public health protection, its application to the development of metrics that can be used to communicate this stringency within an international or national food safety risk management framework is still in its infancy. In particular, the risk assessment tools for linking the establishment of traditional metrics and other guidance for the hygienic manufacture, distribution, and consumption of foods to their anticipated public health impact can be complex and not always intuitive. Furthermore, effective risk assessments generally have to consider the variability and uncertainty associated with risk factors, whereas most risk management decisions which are consistent with the legal frameworks underpinning the authority of most competent authorities must ultimately be simplified to a binary criterion (e.g. “acceptable or not acceptable”, “safe or unsafe”).

### *Scope*

The purpose of this annex is to provide guidance to Codex and national governments on the concepts and principles for the development and implementation of microbiological risk management metrics, including how risk managers and risk assessors may interact during this process.

The guidance provided by the annex should also prove useful to the food industry and other stakeholders who have the responsibility of devising, validating, and implementing control measures that will ensure that, once established, a microbiological risk management metric will be achieved on a consistent basis.

It is beyond the scope of this document to consider in detail the risk assessment tools, techniques, and mathematical/statistical principles that may be pertinent to the development and implementation of specific metrics for a specific food/hazard.

### *Use of the Document*

This annex provides general guidance on approaches to the establishment of microbiological risk management metrics to more objectively and transparently relate the level of stringency of control measures or entire food safety control systems to the required level of public health protection. The annex also addresses the use of these metrics as a means of communicating and verifying risk management decisions. Recourse to microbiological risk management metrics is not always the most appropriate approach to address all food safety management questions. In some cases where a full risk assessment is not available, sound scientific information may be entirely valid and sufficient to inform risk managers, who may decide to implement control measures without directly linking their impact to the public health outcomes. The level of application by competent authorities may vary, taking into account knowledge and availability of scientific information. It is up to competent authorities to prioritize foods relevant to the countries for considering the application of MRM metrics.

This annex should be used in conjunction with the Codex “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius<sup>15</sup>,” “Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999),” “Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007),” “Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007),” “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application” (Annex to CAC/RCP 1-1969), “Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997)” and “Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008)”.

Its application is also dependent on having risk assessment and risk management teams that are familiar with the concepts, tools and limitations of both risk management and risk assessment. Accordingly, it is recommended that the members of such teams use this annex in conjunction with standard references such as the technical information developed by FAO/WHO and the Codex Alimentarius Commission. It is recognized that given the recent elaboration of the MRM metrics concept, there is a need for development of a practical manual to facilitate implementation by countries which have no experience in implementation of these metrics.

### ***Principles for the establishment and implementation of microbiological risk management metrics***

These principles are in addition to those identified in the “Principles and Guidelines for the Conduct of Microbiological Risk Management.”

1. The establishment and implementation of microbiological risk management metrics should follow a structured approach, with both the risk assessment phase and the subsequent risk management decisions being fully transparent and documented.
2. Microbiological risk management metrics should be applied only to the extent necessary to protect human life or health and set at a level that is not more trade restrictive than required to achieve an importing member’s ALOP.
3. Microbiological risk management metrics should be feasible, appropriate for the intended purpose, and applied within a specific food chain context at the appropriate step in that food chain.
4. Microbiological risk management metrics should be developed and appropriately implemented so they are consistent with the requirements of the regulatory/legal system in which they will be used.

### ***Relationship between Various Risk Management Metrics***

A key food safety responsibility of competent authorities is to articulate the level of control that it expects industry to achieve. One tool commonly used by competent authorities has been the development and use of food safety metrics. The metrics employed by competent authorities have been evolving over time as management of food safety issues has moved from a hazard-based approach to a risk-based approach.

#### **Traditional Metrics**

Traditional metrics for establishing the stringency of one or more steps in a food safety control system include PdC, PcC, and MC.

**Product Criterion.** A PdC specifies a chemical or physical characteristic of a food (e.g. pH, water activity) that, if met, contributes to food safety. Product criteria are used to articulate conditions that will limit growth of a pathogen of concern or will contribute to inactivation, thereby decreasing the potential for risk to increase during subsequent distribution, marketing and preparation. Underlying a PdC is information related to the frequency and level of the contamination in the food and/or raw ingredients that is likely to occur, the effectiveness of the control measure, the sensitivity of the pathogen to the control measure, the conditions of product use, and related parameters that ensure that a product will not have the pathogen at an unacceptable level when the product is consumed. Ideally, each of these factors that determine the effectiveness of a PdC would be transparently considered when the criterion was being established.

**Process Criterion.** A PcC specifies the conditions of treatment that a food must undergo at a specific step in its manufacture to achieve a desired level of control of a microbiological hazard. For example, a milk pasteurization requirement of a heat treatment of 72°C for 15 seconds specifies the specific time and temperature needed to reduce the levels of *Coxiella burnetii* in milk by 5 logs. Another example would be specifying the times and temperatures for refrigerated storage which are based on preventing the growth of mesophilic pathogenic bacteria such as *Salmonella enterica* in raw meat. Underlying a PcC should be a transparent articulation of the factors that influence the effectiveness of the treatment. For the milk pasteurization example, this would include factors such as the level of the pathogens of concern in raw milk, the thermal resistance among different strains of the microorganisms, the variation in the ability of the process to deliver the desired heat treatment, and degree of hazard reduction required.

**Microbiological Criterion.** An MC is based on the examination of foods at a specific point in the food chain to determine if the frequency and/or level of a pathogen in a food exceed a pre-established limit (e.g., the microbiological limit associated with a 2-class sampling plan). Such microbiological testing can either be employed as a direct control measure (i.e., each lot of food is

<sup>15</sup> Codex Alimentarius Commission, *Procedural Manual*.

tested and unsatisfactory lots removed) or, in conjunction with a HACCP plan or other food safety control system, as a periodic means of verifying that a food safety control system is functioning as intended. As a technological and statistically-based tool, an MC requires articulation of the number of samples to be examined, the size of those samples, the method of analysis and its sensitivity, the number of “positives” and/or number of microorganisms that will result in the lot of food being considered unacceptable or defective (i.e., has a concentration or percentage of contaminated units exceeding the pre-determined limit), and the probability that the pre-determined limit has not been exceeded. An MC also requires articulation of the actions that are to be taken if the MC is exceeded. The effective use of an MC is dependent on a selection of a sampling plan based on the above parameters to establish the appropriate level of stringency. Since the levels of a pathogen in many foods can change over the course of their manufacture, distribution, marketing and preparation, an MC is generally established at a specific point in the food chain and that MC may not be pertinent at other points. Underlying an MC should be a transparent articulation of the pre-determined limit and the rationale for the sampling plan chosen.

### Emerging Metrics

The increased emphasis on risk analysis as a means for managing food safety concerns has led to increased interest in the development of risk-based metrics that can be more directly related to public health outcomes through a risk assessment process. Three such risk-based metrics that have been defined by the CAC are the FSO, PO, and PC. The quantitative aspects of these metrics have been specifically defined by the CAC,<sup>16</sup> but application of metrics that have variations in their quantitative expression may still satisfy the goals and principles presented in this Annex.

**Food Safety Objective.** The FSO is a metric articulating the maximum frequency and/or concentration of a pathogen in a food at the time of consumption that provides or contributes to the ALOP. An FSO can be an important component of a risk-based system of food safety. By setting an FSO, competent authorities articulate a risk-based limit that should be achieved operationally within the food chain, while providing flexibility for different production, manufacturing, distribution, marketing, and preparation approaches.

Because of the link between FSO and ALOP, FSOs are established only by national competent authorities. Codex can help in establishing FSOs, for instance, through recommendations based on national or international microbiological risk assessments. Food safety objectives should be given effect by actions at earlier stages in the food chain by the competent authority and/or the individual food business operator (e.g. food manufacturer) setting POs, PCs or MCs, as appropriate.

There are two approaches to establishing an FSO. One is based on an analysis of the public health data and epidemiological surveys. The other is based on analysis of data on the level and/or frequency of a hazard in a food to develop a risk characterisation curve linking hazard levels to disease incidence. If such a curve is available for a given hazard, it can be a helpful basis to relate the FSO to the ALOP.

In countries, FSOs can be used:

- to express the ALOP (whether explicit or implicit) as a more useful parameter for the industry and other interested parties;
- to encourage change in industry food safety control systems, or in the behaviour of consumers, in order to enhance food safety;
- for communication to parties involved in food trade;
- as a performance target for entire food chains to enable industry to design its operational food safety control system (through establishing appropriate POs, PCs and other control measures and interaction between the participants of the food chain in question).

Since the FSO relates to the time of consumption, it is unlikely that a competent authority would set an FSO as a regulatory metric due to the unverifiable nature of this point in the food chain.

FSOs may not be universal among all countries and may need to take into account regional differences.

**Performance Objective.** The articulation of a PO by a risk manager provides an operational (see below) risk-based limit in a food at a specific point in the food chain, i.e. the maximum frequency and/or concentration of a microbiological hazard in a food at that point in the food chain which should not be exceeded if one is to have confidence that the FSO or ALOP will be maintained. Since a PO is conceptually linked to the FSO and ALOP, the impact of the steps in the food chain both before and subsequent to the PO should be considered in setting its value. For example, consider a PO for bottled water that specifies that the level of salmonellae after a microbiocidal treatment must be less than  $-2.0 \log_{10} \text{cfu/ml}$ . This would require consideration of the level of salmonellae in the incoming untreated water over a period of time, as well as the effectiveness of the microbiocidal treatment to reduce that level of contamination. The establishment of the PO in relation to controlling the overall risk would also have to consider any post-treatment increases in the level of surviving salmonellae or recontamination of the product prior to consumption.

The frequency and/or concentration of a hazard at individual steps throughout the food chain can differ substantially from the FSO. Therefore, the following generic guidelines should apply:

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<sup>16</sup> Codex Alimentarius Commission, *Procedural Manual*.

- If the food is likely to support the growth of a microbial hazard between the point of the PO and consumption, then the PO will necessarily have to be more stringent than the FSO. The difference in stringency will depend on the magnitude of the increase in levels expected;
- If it can be demonstrated and validated that the level of the hazard will decrease after the point of the PO (e.g. cooking by the final consumer), the PO may be less stringent than the FSO. By basing a PO on the FSO, the frequency of cross-contamination could also be factored into the control strategy. For example, establishing a PO for frequency of salmonellae contamination of raw poultry earlier in the food chain would contribute to a reduction of illness associated with poultry mediated cross- contamination in the steps to follow;
- If the frequency and/or concentration of the hazard is not likely to increase or decrease between the point of the PO and consumption, then the PO and the FSO would be the same.

A MRA can assist in determining the relationship between a PO and an FSO. A MRA can also provide the risk manager with knowledge of hazard levels possibly occurring at specific steps in the chain and of issues regarding the feasibility in practice to comply with a proposed PO/FSO. In designing its food safety control system such that the PO (set by a competent authority or the individual food business) and the FSO (set by a competent authority) are met, the individual food business will have to make provisions reflecting its ability to consistently meet these standards in operational practice, including consideration of a margin of safety.

The individual food business may find it beneficial to establish its own POs. These POs should normally not be universally common and should take into account the position of the business within the food chain, the various conditions at the subsequent steps in the food chain (probability and extent of pathogen growth under specified storage and transport conditions, shelf-life, etc.) and the intended use of the end products (domestic consumer handling, etc.). Although compliance with POs is not always verified by analytical means, verifying that a PO is being consistently met can be achieved by measures such as:

- monitoring and recording of pertinent validated control measures, including establishment of a statistically-based, validated MC for end products;
- monitoring programs on the prevalence of a microbial hazard in a food (especially relevant for POs established by competent authorities).

**Performance Criterion.** A PC articulates an outcome that should be achieved by a control measure or a series or a combination of control measures. Generally, a PC is used in conjunction with a microbiocidal (e.g., thermal treatment, antimicrobial rinse) or microbiostatic (e.g., refrigeration, water activity reduction) control measure. A PC for a microbiocidal control measure expresses the desired reduction of the microbial population that occurs during the application of the control measure (e.g., 5-log reduction in the levels of *L. monocytogenes*). A PC for a microbiostatic control measure expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied (e.g., less than a 1-log increase in *L. monocytogenes* during refrigerated distribution of a ready-to-eat food). In many instances, the PC describes the outcome that is needed in order to achieve a PO at a specified point in the food chain. There are a number of factors that would have to be considered in reaching a decision on the value of a PC, such as the variability of pathogen levels in raw ingredients or the variability associated with a processing technology.

PCs are generally set by individual food businesses. A PC may be set by national governments for a specific control measure, where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.

Such PCs are often translated by industry or sometimes by competent authorities into a PcC or a PdC. For example, if a PC indicated that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criteria would stipulate the specific time and temperature combination(s) that would be needed to achieve the PC. Similarly, if a PC required that an acidification treatment of a food reduce the rate of growth of a hazard to less than 1-log in two weeks, then the product criterion would be the specific acid concentration and pH that would be needed to achieve the PC. The concepts of process criteria and product criteria have been long recognised and used by industry and competent authorities.

### **Integration of Microbiological Risk Management Metrics Within a Food Safety Control System**

A key concept underlying the "General Principles of Food Hygiene" (CAC/RCP 1-1969) is that key control measures must be integrated into a "farm-to-table" food safety control system in order to consistently produce a food product that achieves the desired level of public health protection (i.e., the ALOP). Since the purpose of establishing and implementing microbiological risk management metrics is to articulate and verify, in an objective and transparent manner as far as possible, the stringency of control measures needed to achieve a specific level of public health protection, it is likely that metrics may be implemented at multiple points along the food chain. A key to understanding the development of such metrics is an appreciation that the metrics implemented along a food chain should be interconnected. There are two types of interconnections. The first is the relationship among different types of microbiological risk management metrics at a specific step in the food chain. The second is that ideally metrics implemented along the food chain would be integrated such that the establishment of a metric at one point in the food chain can be related to the outcome at another and ultimately to the desired public health outcome.

The PO is likely to be the primary risk-based metric used by competent authorities to articulate the level of control (i.e., frequency and/or concentration) of a hazard at a specified point in the food chain. Once articulated, the PO in conjunction with additional information can be used to derive other microbiological risk management metrics. As a simplified example, consider a PO after a heat treatment of a food is a *Salmonella* concentration of  $\leq -4.0 \log_{10}(\text{cfu/g})$ . If the maximum level of *Salmonella*

likely to occur in the food prior to heating is  $+1.0 \log_{10}(\text{cfu/g})$ , then the PC for this step would be a 5-log reduction. The PC value in conjunction with information on the thermal resistance of *Salmonella* could be used to articulate specific time/temperature combinations (i.e., PcC values) that would achieve the 5-log reduction. The same concept underpins the relationship between a PO and an MC. In this instance, the MC is used to verify that a PO is not being exceeded. The PO value in conjunction with information on the likely variance of the pathogen's presence and the level of confidence required by the risk managers is used to develop a sampling plan and decision criteria associated with an MC. In general, the microbiological limit associated with an MC will have to be more stringent than its corresponding PO to take into account the degree of confidence required that the food does not exceed a PO. It is also important for risk managers to appreciate that, in the absence of an explicit PO, the establishment of microbiological risk management metrics such as a PC, PcC, PdC, or MC, in combination with the additional information described above, will allow the PO for a control measure to be inferred.

As indicated earlier, the establishment of microbiological risk management metrics at different points along the food chain should take into account the changes in the frequency and/or concentration of a hazard that occur during a specific segment of the food safety control system if the desired level of overall control is to be achieved. Recent advances in MRA are increasingly allowing microbiological risk management metrics at different points to be related to each other and to the overall level of protection achieved by the food safety control system. The ability to relate PO and other metrics implemented at intermediate steps in the food chain to a PO or FSO established by a competent authority would be a useful tool for industry to design and verify that their control measures are achieving the desired level of control.

The integration of microbiological risk management metrics both at a specific point in the food chain and between points in the food chain will require the availability of subject matter experts and appropriate models and data pertinent to the food product and the processes and ingredients used in its manufacture, distribution, and marketing.

### **Key Risk Assessment Concepts Related to the Development and Use of Microbiological Risk Management Metrics**

An integral part of the development of food safety metrics is a consideration of the variability inherent in the food ingredients, the control measures, and ultimately the food that determine the range of results that can be expected when a food safety control system is functioning as intended. Likewise, any uncertainties associated with the parameters affecting the food safety control system should be considered when establishing an integrated set of food safety risk management metrics. Both variability and uncertainty can be evaluated using QMRA techniques in conjunction with an appropriately designed risk assessment, providing a tool for formally evaluating and documenting how these important attributes were considered in the decision-making process.

One of the challenges in establishing and integrating the risk management metrics described above is translating the results of a risk assessment into a set of simple limits that can be communicated and implemented. This reflects the fact that QMRAs are often based on probabilistic models that typically employ unbounded distributions (e.g., log-normal distributions for microbial populations) that have no maximum value. Thus, there is calculable probability that a metric could be exceeded when the control measure or food safety control system is functioning as intended. For example, if a control measure was designed to ensure that the level of bacteria at an intermediate processing step had a geometric mean of  $\log_{10}(\text{cfu/g}) = 3.0$  and a standard deviation of 0.3 and was operating as intended, it would be expected that approximately one serving in 200 would have  $\log_{10}(\text{cfu/g}) = 4.0$  and approximately one serving in 1,000,000 would have  $\log_{10}(\text{cfu/g}) = 4.7$ .

The implication of this concept is a characteristic inherent to the use of microbiological risk management metrics. Using the example above, if it is assumed that an MC was set by the risk manager to have a degree of confidence that a lot having servings that exceeded  $\log_{10}(\text{cfu/g}) = 4.5$  would be detected and rejected, any occasion when the MC is exceeded will be considered a loss of control, even though there is a small possibility that the system may be working as intended. Microbiological risk management metrics will have to be made "operational" by deciding what portion of a potentially open-ended distribution for an "under control" control measure will be considered as exceeding the limit and the degree of confidence, such that any serving of food exceeding that value is rejected (e.g., 95% confidence that 99% of servings of a ready-to-eat food have less than 1 *Salmonella* per 100 g). While there are techniques that can be used to include some consideration of distributions within risk management decisions and verification criteria (e.g., 3-class attribute sampling plans), a series of operational assumptions will be required for any microbiological risk management metric. A critical component of establishing such a metric is ensuring that the underlying assumptions are understood by the risk managers and interested parties.

### **An Example of a Process for Establishing and Implementing Microbiological Risk Management Metrics**

While the development of microbiological risk management metrics should follow a structured approach, the processes and procedures put into place by competent authorities for the establishment of integrated microbiological risk management metrics should be highly flexible in relation to what metric is initially used to begin relating the performance of the food safety control system to its public health outcomes. The process can begin with an articulation of a level of disease control that must be achieved (i.e., ALOP), the exposure level that should not be exceeded at consumption (i.e., FSO), a level of control of a hazard that must be achieved at a specific point in the food chain (i.e., PO), a required processing outcome at a specific step (PC), an MC, etc.

When development of a microbiological risk management metric is being considered, there will likely be a need for close communication and mutual understanding between risk assessors and risk managers. The development of specific microbiological risk management metrics will likely require the formation of appropriate risk analysis teams consisting of appropriate subject matter experts. Scientific advice and data for specific hazard/food applications should be acquired from appropriate scientific organizations, competent authorities, process control experts or related sources of scientific expertise.

Where appropriate, risk assessors and risk managers may wish to consider the following protocol, or some variation thereof, as a means of ensuring the principles for microbiological risk management lead to transparent, informed decisions.

- a. The risk managers commission the risk assessors to develop a risk assessment or other suitable scientific analysis that can inform the possible development of microbiological risk management metrics.
- b. The risk managers, after consultation with the risk assessors, select one or more sites along the food chain for the product where a risk management metric may be pertinent, useful, and practical.
- c. The risk assessors use the risk assessment to evaluate how different values for the microbiological risk management metric being considered are related to the consumers' exposure and the subsequent public health outcomes. Whenever feasible, the risk assessors should provide the risk managers with an array of values for potential microbiological risk management metrics, information on uncertainty that may indicate a need for margins of safety and the corresponding level of protection expected if implemented.
- d. The risk assessors use the risk assessment and related tools to ensure that the microbiological risk management metrics being considered by the risk manager are consistent with each other, appropriately taking into account the increases and decreases in hazard levels that may occur during that portion of the food chain.
- e. The risk managers evaluate the practical feasibility of achieving the specific level of stringency through implementation of the metric being considered, including consideration of how to verify that the microbiological risk management metric is effectively met.
- f. Risk assessors provide advice on the public health implications of non-compliance with a metric being considered.
- g. The risk manager selects the microbiological risk management metrics to be implemented, their level of stringency, and the strategy for their implementation.
- h. At the request of the risk managers, the risk assessors calculate additional microbiological risk management metrics that may be derived or inferred from the decision in step g.
- i. Risk managers implement, in conjunction with industry, the risk management metrics.
- j. Risk managers review implemented microbiological risk management metrics for the degree of implementation, efficacy, and ongoing relevance. The criteria for review should be decided when the microbiological risk management metrics are initially implemented. For instance, review can be periodic and/or may also be triggered by other factors such as new scientific insights, changes in public health policy, or changes in the food chain context in which the metrics are applied.