

# The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies:

Metrics to improve food safety

## Report

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### A JOINT FAO/WHO EXPERT MEETING



Federal Ministry of  
Food, Agriculture and  
Consumer Protection



World Health  
Organization





The Use of Microbiological Risk Assessment  
Outputs to Develop Practical Risk Management  
Strategies:  
Metrics to Improve Food Safety

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## Foreword

The Codex Alimentarius Commission adopted Principles and Guidelines for the Conduct of Microbiological Risk Assessment in 1999. Since then numerous microbiological risk assessments have been undertaken at both national and international levels and the methodology and tools for this type of risk assessment continue to evolve and advance.

The establishment of a clear understanding of how best to use this tool in elaborating risk management decisions has been more difficult. In 2002 FAO and WHO convened an expert meeting to develop principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. The output of this meeting was enlightening in many respects, particularly in providing guidance on preliminary risk management activities. However, it was less successful in providing guidance on how to use MRA to establish specific numerical targets or standards.

Since then Codex Alimentarius has adopted definitions of food safety targets that could be established by means of risk assessment i.e. food safety objective, performance objective. Although agreeing on definitions, Codex at that time was unable to provide guidance as to how these targets could, in practice, be determined and achieved. As the same time FAO, WHO and Codex observed the difficulties within the Codex system of utilising the MRA's developed by FAO and WHO at the request of Codex.

In 2004 FAO and WHO agreed that more work was needed in this area and this was endorsed by the Codex Committee on Food Hygiene. FAO and WHO then initiated a programme of activities to address this, with the ultimate objective of providing guidance in the application of MRA to establish specific numerical targets or standards. These activities have included the establishment of a number of working groups to look at the issues and the results of microbiological risk assessment to develop food control measures, with particular emphasis on the establishment of targets or metrics and their application. The outputs of these working groups and other relevant documentation were then considered and discussed by an expert meeting convened in Kiel, Germany on 3 – 7 April 2006.

This report aims to summarise the recent international discussions and their outcomes and provide an overview as to the current status in terms of the application of MRA in food safety management. Although good progress has been made in recent years, many challenges remain.



## Executive Summary

In recent years “risk-based” approaches, based on the best available scientific information, have been recognized as a means of enhancing the ability of food safety risk management to meet its primary goal of protecting public health, as well as ensuring access to an adequate food supply and facilitating trade. Such an approach implies that actions, regulations, guidelines, and standards are constructed and formulated according to specific knowledge of “risks” to life and health. The practical aspects of developing and implementing of a “risk-based” standards introduce new challenges.

Microbiological risk assessment (MRA) is now well recognized as a risk management decision-support tool. When properly designed, a MRA is an objective, systematic evaluation of relevant scientific knowledge to help the risk manager make an informed decision about how to reduce the risk posed by a food safety issue. It is a particularly useful tool in enabling the risk manager to consider and compare risk management options and derive food safety control measures. Together with other tools, for example epidemiology based tools (e.g. source attribution) and economic analysis, it can provide a sound scientific foundation for “risk-based” management systems and control measures.

This report describes some of the recent international activities, which included undertaking case studies and convening an expert meeting, and the outcomes of discussions on the use of MRA in microbiological risk management. In particular, it addresses the progress made and the challenges being faced in elaborating practical guidance on the use of MRA outputs to develop practical risk management strategies. It should be noted that the meeting was only able to begin the process of developing practical guidance in this area. The participants (a) summarized the current state of play, (b) used case studies prepared in advance of the meeting to identify the technical areas where guidance is needed (c) identified priority issues which will need further discussion and elaboration in order to provide the practical guidance requested by the Codex Committee on Food Hygiene and required by FAO and WHO member countries. Thus, this report should be considered a step in the continuing international process to establish a sound technical basis for adopting a risk analysis approach to microbiological food safety concerns.

The role of MRA in food safety risk management is varied and the way in which an MRA is developed should directly relate to the needs of risk managers, as far as possible according to data or resource limitations. Taking this into consideration the meeting sought to outline the range of potential applications of MRA in risk management including its role in the development of quantitative risk-based microbiological targets or *metrics*<sup>1</sup>, the selection and evaluation of control measures, the articulation of levels of control expected of food safety systems in a manner consistent with the goals of the Codex Alimentarius and the World Trade Organization and the verification of compliance.

Recently there has been particular focus on the use of MRA to establish and/or implement quantitative risk-based microbiological targets or metrics such as Food Safety Objectives (FSOs), Performance Objectives (POs), and Performance Criteria (PCs), that are intended to relate public health goals with the degree of stringency required of food safety systems and control measures to achieve these goals. While these targets have been defined by Codex there is little experience to date regarding their establishment or implementation. The

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<sup>1</sup> See section 1.2 “Terminology”.

meeting considered FSO, PO and PC to be *intermediate targets*<sup>2</sup>, given that they provide the means to link actual control measures to public health outcomes. While it is considered that MRA has a critical role in their establishment and implementation, the means by which MRA can be used to achieve this was an important area of discussion of the meeting. It was noted that while an FSO may be used as a metric for translating control measures into public health outcomes, PO and PC are more likely to be the metrics used for establishing the stringency of a food safety system. An important reason for this is that PO and PC can be utilised at points in the food supply chain where control measures can be implemented and verified, through the implementation of appropriate microbiological criteria, processing criteria and product criteria.

An important consideration was the type of MRA that could be used to establish such quantitative targets. Quantitative MRA can be deterministic or probabilistic. While deterministic risk assessment, being based on single value inputs and outputs provides a relatively straightforward means of using MRA to develop such targets, this comes at a cost in terms of accuracy, limited insights into uncertainty and a tendency to focus on extreme situations, e.g. worst-case scenarios. Probabilistic risk assessment provides the means to overcome these disadvantages and in principle offers the best opportunity for operationalizing intermediate targets. However, considering that the inputs and outputs of the probabilistic approach is a distribution of values, this poses a significant challenge in terms of how to express the outcome as a target to be achieved by appropriate control measures and for taking decisions that are consistent with the legal systems of various countries.

One of the advantages of a properly designed deterministic model is the ability to move forwards and backwards in the model to, for example, determine possible values for a PO and to select the best points in the chain for POs. The more complex nature of probabilistic risk assessments makes it more complicated to “back calculate” starting at the FSO or a PO to determine the value of a PO earlier in the food chain. The meeting provided general guidance on how this and other difficulties could be avoided, and identified several other technical issues that need to be considered to successfully develop guidance to countries and others who want to take advantages of the strengths of these decision tools.

Substantial discussion was devoted to whether the current definitions of FSO, PO and PC are fully compatible with what is currently accepted as the outputs of probabilistic risk assessment. This revolved around the definitions’ use of “maximum.” Some experts felt that this was inconsistent with the distributions involved with probabilistic risk assessments whereas others were of the opinion that the definitions were currently flexible enough to allow maximum to be operationally defined. Further discussions are needed to consider how this discrepancy could be resolved.

A well designed risk assessment provides the means to evaluate and compare the effects of different control measures on public health risk to consumers (i.e., risk per servings) or risk to a country (i.e., risk per annum) on an industry wide basis. This *direct* application of MRA has been demonstrated by a number of risk assessments at both national and international level and is widely recognized as one of the strengths of MRA.. However, despite its well recognized utility, this approach may be restrictive, particularly when applied to foods where there is diversity in the way these foods are manufactured and where there are

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<sup>2</sup> See section 1.2 “Terminology”.

multiple approaches to managing risks. In such cases the establishment of intermediate targets may be more desirable and practical.

Risk management does not end with the selection of appropriate control measures. It must be followed up with monitoring activities to determine the level of compliance. The effectiveness of a particular control measure can be highly influenced by the level of compliance with that measure. Too high a level of stringency may reduce the level of compliance, whereas a very high degree of compliance may be achieved with something slightly less stringent. MRA allows consideration and comparison of such scenarios to facilitate the selection of the most appropriate risk management option.



# 1 INTRODUCTION

## 1.1 Background

Food safety risk management can be described in general terms as the process of weighing control alternatives by government (and international standard-setting bodies) in consultation with interested stakeholders, taking into account scientific information on risks to consumers as well as other relevant inputs (e.g. economics, technical feasibility, societal preferences), and choosing and implementing food safety measures as appropriate.

During the course of the past ten years, FAO, WHO, the Codex Alimentarius Commission and individual countries have made significant progress in the development of a generic Risk Management Framework (RMF). This framework identifies the different activities that need to be conducted in a structured, ongoing and iterative manner to manage food safety risks. It is a systematic process that uses the results of MRA and other scientific evaluations to develop effective risk management options for implementation at appropriate steps along the food chain. Previous meetings in Kiel, Germany focussed upon the interaction between assessors and managers of microbiological hazards (2000) and incorporation of microbiological risk assessment in the development of food safety standards (2002). In 2005 FAO/WHO reported to the 37<sup>th</sup> Session of the Codex Committee on Food Hygiene (CCFH) their plans to undertake work on “Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs”. In order to ensure that such work provided information that would be of use to Codex, FAO/WHO asked CCFH to identify specific areas of interest. In response CCFH highlighted their needs in this area through the development of a Discussion Paper on the Needs of CCFH for the Provision of Scientific Advice by FAO/WHO on the Application of Risk Assessment to Risk Management (Annex I).

During application of a risk management framework, different types of risk management options can be considered. In support of this and building on the work of a number of countries that have developed national risk assessments, FAO and WHO have jointly developed a range of microbiological risk assessments in response to specific requests from the CCFH. While answering risk management questions posed by CCFH, they have also evolved into comprehensive resource documents on the food safety problems of concern, as well as on risk assessment methodology itself.

Over the last two years there has been particular focus at the international level on the use of MRA to establish and/or implement quantitative risk-based microbiological targets (or metrics) such as Food Safety Objectives (FSOs), Performance Objectives (POs), and Performance Criteria (PCs), that are intended to relate public health goals with the degree of stringency required of food safety measures and systems to achieve these goals. In this context, such targets potentially play an important role in food safety risk management by articulating the level of control of identified risks needed to achieve the desired level of public health protection. They can also serve as a basis to more scientifically establish traditional “operational” control measures, for example microbiological criteria or process criteria that are employed to establish the level of control required and verifying that that level of control is achieved.

## 1.2 Terminology used in the report

The terminology that is used in relation to food safety risk management is extensive and varied. Some of the terms used in the context of this report and their intended meaning are:

- Control measure: any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.<sup>3</sup>
- Risk management option: the risk manager may have available to him/her a range of potential actions or interventions, in other words options, that could potentially be implemented. It is the role of the risk manager to ensure that such options are identified and the acceptable one(s) selected for subsequent implementation. In doing this, risk managers need to consider the suitability of the potential risk management options to reduce the risk posed by a food safety issue to an acceptable level.<sup>4</sup>
- Metrics: quantitative expressions that indicate a level of control at a specific step in a food safety risk management system. For the purpose of this report the term “metric” is used as a collective for the new risk management terms of food safety objective, performance objective and performance criteria, but it also refers to existing microbiological criteria.<sup>5</sup>
- Intermediate targets: for the purposes of this document FSO, PO and PC are considered to be and referred to as intermediate targets.

## 1.3 Overview of microbiological risk management

The microbiological risk management (MRM) process is described by Codex in their draft principles and guidelines for the conduct of MRM (see Annex VI) and a diagrammatic overview of the process is presented in Figure 1, below. The ultimate aim of any MRM process is the availability of safe food and improved levels of consumer protection. Risk managers are responsible for choosing and implementing food safety control measures, taking into account available scientific information. Within this process, risk managers may undertake different tasks ranging from the establishment of public health goals, articulating the appropriate levels of protection, enforcing control measures, evaluating or verifying the performance of their management decisions to ensuring the country meets its obligations under the SPS Agreement.

For risk managers to make informed decisions, it is critical they understand whether a risk management program will deliver an expected public health outcome. This is particularly relevant when attempting to determine the economic consequences of a risk management approach or the equivalence of approaches. The ability to use a risk assessment to directly consider the impact of different risk mitigation strategies on the public health outcome is a powerful tool.

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<sup>3</sup> See Codex Alimentarius Food Hygiene Basic Texts, Hazard Analysis and Critical Control Point System (HACCP) and Guidelines for its Application, Definitions. Available at: [ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene\\_2003e.pdf](ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2003e.pdf).

<sup>4</sup> Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 5; 6.1 Identification of the available MRM options for Codex (ALINORM 05/28/13, Appendix III).

<sup>5</sup> See Codex Alimentarius Food Hygiene Basic Texts, Principles for the Establishment and Application of Microbiological Criteria for Foods, 1. Definition of microbiological criteria (CAC/GL 21-1997). Available at: [ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene\\_2003e.pdf](ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2003e.pdf).

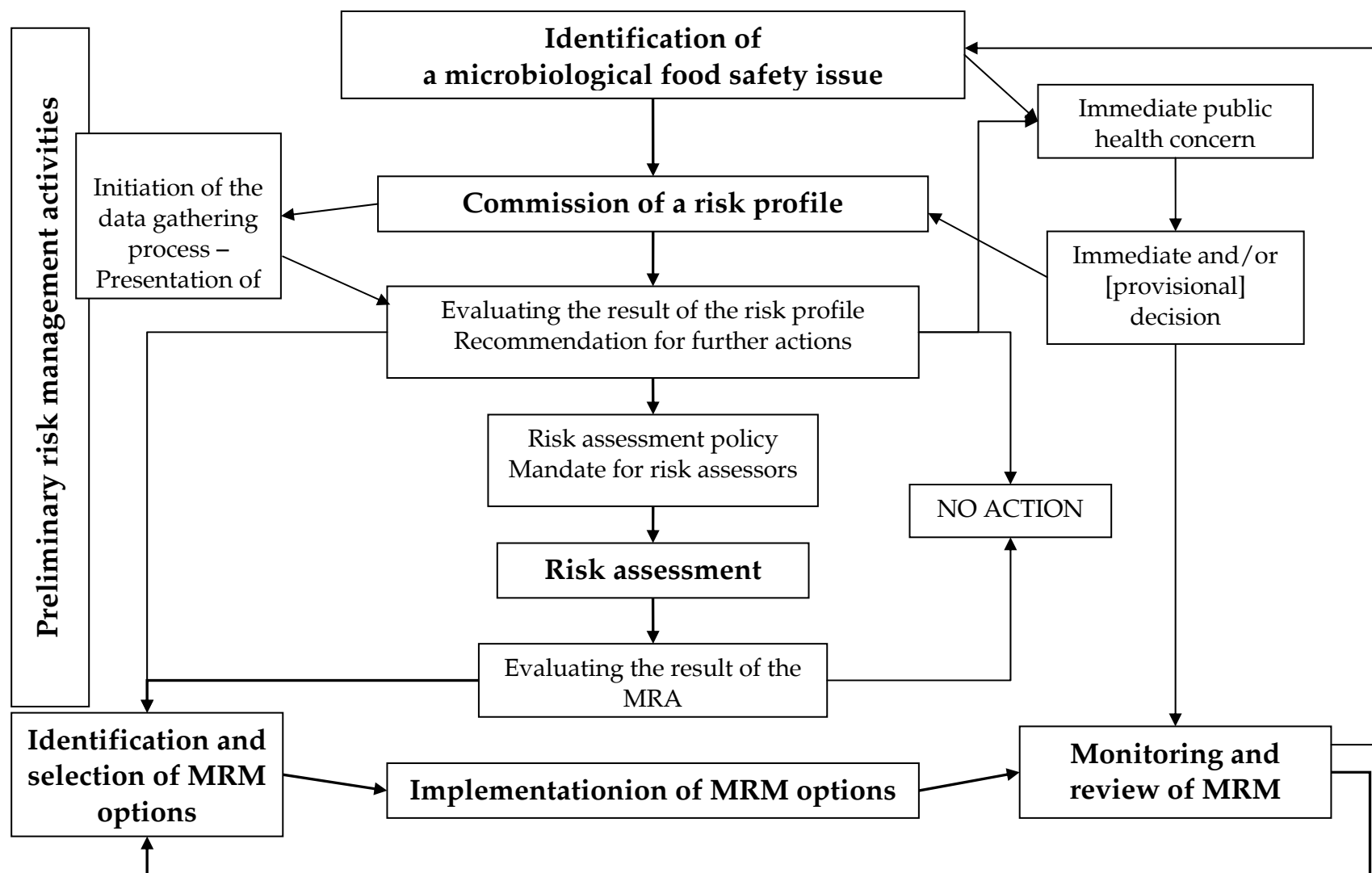
In recent years “risk-based” approaches, based on the best available scientific information, have been recognized as a means of enhancing the ability of food safety risk management to meet its primary goal of protecting public health, as well as assuring access to an adequate food supply and facilitating trade. Such an approach implies that actions, regulations, guidelines, and standards are constructed and formulated according to specific knowledge of “risks” to life and health, thus, the practicalities of implementation of a “risk-based” standard introduce new challenges.

Risk-based management actions that are aimed at achieving a level of health protection which can be explained and validated in terms of “risk” to human health may be expressed in terms of a public health goal, the appropriate level of protection (ALOP) currently achieved or other relevant term. Public health goals are set, usually by governments or public health bodies, to inspire action to improve the public health status and reduce disease burden. Setting such goals, which can range from the general to the specific, requires consideration of the current health status and disease burden as well as feasibility in terms of how to achieve the goals and measure the degree of achievement. Public health status is a measure of the current health situation in the population and can also be expressed in general or specific terms. This may be used as a basis from which to establish future public health goals or as a measure of the effectiveness of risk management actions. A particular expression of the current public health status is the Appropriate Level of Protection (ALOP), which originated from the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. In contrast to a public health goal, an ALOP is an expression of the level of protection in relation to food safety that is currently achieved. It is not an expression of a future or desirable level of protection.

Risk management which focuses on food safety systems achieving a specified level of performance can promote public health and international trade, while still allowing for innovation and different approaches for meeting that desired level of protection. As the application of such approaches becomes more widespread, the adoption of risk-based management systems by countries becomes more critical for trade. While WTO promotes the harmonization of international standards and Codex develops the relevant food safety standards, a country may in some cases need to exceed the international standard. In order to execute this right a justification is required, which can be validly provided through the implementation of risk management actions based on risk assessment.

### **1.3.1 Food safety management in practice**

As food safety management approaches have evolved there has been a move towards a whole food chain approach. This recognizes the many contributors to ensuring food safety all along the food chain. But importantly from a management perspective it highlights the need for collaboration of different institutions and ministries at national or government level. Food safety is no longer the responsibility of a single ministry such as those responsible for agriculture or health. Successful food safety management recognizes the importance of collaboration between the relevant sectors and well designed risk-based management systems provide the mechanism for such collaboration.



**Figure 1:** Diagrammatic overview of the microbiological risk management framework (from the Draft Codex Principles and Guidelines for the Conduct of Microbiological Risk Management).

Sometimes these provisions relate to one specific step but more often they reflect the integrated control measures of all steps prior to a specific site in the food chain. The level of control at a designated step in the food chain must be sufficient to take account of the likely dynamics of the hazard in subsequent steps. The provisions for hazard control may be collectively referred to as the food safety management system.

Food safety management systems exert their control through the control measures that are put in place. The stringency of these control measures will determine the overall level of control that will be achieved by a food safety system. The selection of control measures for a step depends on the food to be produced, what effects previous and subsequent steps in the food chain have on the level of the hazard, technologies available, and many other aspects. The selection should also take into account the level of control over a hazard that is required at the particular step. This is often referred to as the required “stringency”. Whether this stringency is achieved will depend on the proper implementation and performance of the control measures. Therefore, along food supply chains, control measures are implemented within systematic management systems such as Good Hygiene Practices (GHP) and a Hazard Analysis and Critical Control Point (HACCP) system, which help assure the selection, systematic implementation and monitoring of valid control measures.

It is the performance of the food safety management system, both in terms of the stringency that it is designed to achieve and the degree to which that system is consistently implemented, that determines the extent of control achieved over a hazard and thus the risk associated with the final food product. The hazard level at consumption is a primary determinant of risk to the consumer, either on a population level or a per serving level. The risk to public health can be quantified based on knowledge of the relationship between the dose of the hazard and its impact on the consumer’s health.

### **1.3.2 Using MRA in the selection/evaluation of intermediate targets**

The expected stringency of measures implemented to achieve the desired level of control in a food safety system can be communicated in different ways, for example the stipulation of manufacturing requirements through the use of process criteria or product testing (e.g., microbiological criteria). The use of such measures involves the establishment of an implicit or explicit limit to the hazard level and/or frequency at a specific point. The establishment of limits provides distinct advantages to both risk managers and the food industry, by clearly articulating the level of control expected. When done on an industry wide basis, this establishes a “level playing field” among companies in the industry. If done with a focus on the level of control required, rather than on a specific technology or practice, such limits provide enhanced flexibility as to the approaches and technologies used to achieve the required level of control .

Such limits have been traditionally established through expert advice and related to a certain level of stringency at a specific step in or at the end of the food chain that was considered to be adequate. However, within a risk-based food safety management system it is possible to more transparently and objectively relate the establishment of such limits to the intended public health outcome. In the draft guidance provided by Codex on such a system (Annex VI), it is proposed to use the terms FSO, PO and PC to communicate the limits required at specific points in food supply chains in an explicit way to the affected food industry.

## 1.4 Recent activities at the international level

Recognizing the need to establish practical guidance, FAO and WHO, in late 2004 prepared a concept paper to define their future program of work on the “*Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs*” (Annex II). At that time a call for experts was also issued in order to identify potential contributors to this activity. As part of the planning process this paper was made available to the 37<sup>th</sup> session of the CCFH (March 2005, Buenos Aires). In response the committee prepared a discussion paper on this issue requesting that FAO/WHO more explicitly focus future work on the development of practical guidance on how to establish FSOs and microbiological criteria derived thereof, on the basis of risk assessment outputs (see Annex I, p.36).

Taking into account the areas for consideration identified by Codex the objective of the FAO/WHO work was defined as:

*The elaboration of guidelines for the use of the outputs of qualitative and quantitative microbiological risk assessments in developing or determining practical strategies and risk management standards for microbiological hazards in foods.*

In order to achieve this, a range of issues were considered. These included identification of:

- The difficulties or barriers that have been encountered to date in developing practical MRM guidance based on the outputs of MRA and associated or relevant scientific information. What is missing? What can be done to overcome these barriers?
- The types of risk management decisions/actions that would benefit from the inclusion of a MRA in combination with other scientific and technological information.
- The lack of practical guidance on how MRA can be used to enhance MRM activities related to the development of Codes of Hygienic Practice or the setting of critical limits in HACCP systems for control measures at primary production, processing, and marketing levels.
- The availability of techniques for modifying a MRA developed at a national and international level so that it is valid for use by another country or risk management system.
- The need to be able to account for regional, cultural and geographical differences in risk management approaches across the world.
- MRA’s may be qualitative or quantitative in nature so it is necessary to consider how the type of MRA will impact the way it is used in risk management.
- The technical, economic, educational, and data limitations that would hamper the development of a MRA and its application to risk management processes.

Considering the wide range of issues to be addressed it became clear that a stepwise approach was warranted. The first step taken was to establish seven working groups to begin addressing the various issues identified above. While one group focussed on the overarching issues and identifying the difficulties faced and the perceived drawbacks of using MRA in risk management, each of the other groups undertook a case study to evaluate the application of MRA in risk management with particular focus on the establishment of targets. Each working group used a different pathogen/product MRA. The six case studies were:

- *Staphylococcus aureus* in cheese
- *Escherichia coli* O157:H7 in meat
- *Vibrio vulnificus* in oysters
- *Listeria monocytogenes* in smoked fish
- *Salmonella* Enteritidis in eggs
- *Campylobacter jejuni* in broiler chickens

Each working group documented its experience in terms of the process it went through to address its task. Based on the assumption that a specific risk management system is being established or already in place, some of the tasks of the case study working groups were as follows:

- Develop an approach for establishing a FSO and any related relevant metrics based upon the results of the MRA and consider how an FSO and related criteria be integrated into traditional food safety management tools such as HACCP and GHP's?
- Consider how to use MRA and other available scientific information to evaluate the efficacy of specific risk management measures including assessing the equivalence of different risk management options.
- Consider what metrics associated with a specific risk management measure could be used to monitor the overall performance of the system and/or specific measure and are necessary for the review its efficacy.

As indicated by the above list the development of guidance on the use of MRA is far from straightforward and while it appears to be possible in some cases it is not necessarily very simple or clear-cut.

A list of the working group members is provided in Annex III and the key findings of the case studies are provided in Annex IV. The complete background papers will be made available on the FAO and WHO websites.

The second step was to use these case studies and framework document, together with other relevant documentation such as the draft Codex texts on MRM (see Annex VI), as the basis for the discussions at an expert meeting, and to contribute to the ultimate objective of developing practical guidance with a focus on the establishment of microbiological targets for risk management of microbiological hazards in foods.

## **1.5 Overview of expert meeting**

The expert meeting was held in Kiel, Germany from 3-7 April 2006, and was hosted by the Federal Research Centre for Nutrition and Food in collaboration with the German Ministry of Food, Agriculture and Consumer Protection. The meeting was opened by Dr Andrea Sanwidi (Federal Ministry of Food Agriculture and Consumer Protection). A total of 23 experts from 15 countries participated in the meeting (Annex V). Participants elected Mr Alan Reilly as chairperson of the consultation and Dr Judith Hilton as rapporteur.

The framework document and case studies were made available to all participants in advance of the meeting, and overviews were presented at the commencement of the meeting in order to facilitate discussion. In addition, the FAO/WHO secretariat presented an

overview of the aims of the meeting and possible thematic areas for discussion. Participants then identified a series of questions and issues to be addressed and, based on this and on the areas for consideration highlighted by CCFH, three main thematic areas were identified. These were:

- The role of MRA in articulating Appropriate Levels of Protection (ALOP) or public health goals;
- The role of MRA in setting FSOs and/or POs, and PCs, such as microbiological criteria, product criteria and process criteria;
- The role of MRA in establishing and evaluating control measures.

Participants were placed into three working groups, each of which addressed one of the three thematic areas. In their discussions, groups were also asked to bear in mind a number of cross-cutting issues. These were the use of terminology in a way that was helpful, rather than a hindrance, to the risk manager, applicability of the guidance to both developed and developing countries, geographical variations, and the diversity of ingredient sources, manufacturing technologies, marketing strategies and consumption profiles.

## **1.6 Objective of report**

This report aims to provide an overview of food safety risk management at the current time and to illustrate the value of MRA in establishing and implementing food control measures. In this context, the current state of play in using MRA to establish food safety targets and their likely utility in food control programmes is presented. Work will continue at the international level to provide a strong technical basis for the most effective and practical utilisation of MRA in food safety.

## **2 USE OF MRA OUTPUTS IN THE MRM PROCESS**

In order for a risk assessment to provide the type of output that is useful to the risk manager there is a need for structured interaction between the risk managers, risk assessors, and risk communicators that fosters the necessary exchange of information and interpretation while maintaining the functional separation of the risk assessors and risk managers. This is part of the preliminary risk management activities component of the risk management framework which has been addressed in detail in a previous expert meeting<sup>6</sup>.

MRA can provide valuable information about the complex dynamics of pathogen behaviour and transmission along the food chain. It can thus be used, within the limits of its design, in a predictive manner. Within these design limitations of which risk managers should be aware, MRA is a particularly useful risk management tool for evaluating the impact of interventions and predicting the effect of potential interventions.

### **2.1 Tools for informing the MRM process**

Effective management of risk arising from microbiological hazards is technically complex and the implementation of sound, scientifically justifiable measures requires the use of various tools, data and information. Basing food safety management approaches on science means that decisions, actions, regulations and standards are based on objective, reliable and verifiable scientific and technical information, combined with robust data and sound scientific expert judgement and /or advice.

When available, the outputs from various decision support tools, such as MRA, epidemiology based tools (e.g. source attribution) and economic analysis, can assist risk managers in their tasks, particularly in the evaluation and selection of appropriate risk management options. These decision support tools can be used in isolation or combined with others. They can also be used to demonstrate a linkage between public health goals and management interventions. As these tools evolve and become more sophisticated, consideration as to how they may be used most effectively is important. As they are still relatively new tools, their use in microbiological risk management continues to be an area of development.

### **2.2 Microbiological risk assessment (MRA)**

An MRA is an objective, systematic evaluation of relevant scientific knowledge to help the risk manager make an informed decision about how to reduce the risk posed by a food safety issue. It is a particularly useful tool in enabling the risk manager to consider and compare risk management options and derive food safety control measures. MRA can be applied, starting from the dynamics of the hazard in the food chain, using predictive models to estimate the outcomes in terms of public health. In general, MRA provides a high level of detail concerning microbial events that occur along the food chain and valuable information about the complex dynamics of pathogens during food processing. While MRA can be used

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<sup>6</sup> FAO/WHO. 2002. Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. Report of a joint FAO/WHO expert consultation. Kiel, Germany 18 – 22 March 2002.

to predict actual public health outcomes, some experts are of the opinion MRA is insufficient in this regard particularly because of the limited availability of dose-response information.

For risk managers to make informed decisions, it is critical they understand whether a risk management program will deliver an expected public health outcome. This is particularly relevant when attempting to determine the economic consequences of a risk management approach or the equivalence of approaches.

### **2.2.1 Factors influencing the type of risk assessment undertaken**

Food systems are complex and microbiological risk assessments are simplified representations of the food system and its impact on human health. Risk assessments are often divided into two groups, *qualitative* and *quantitative*, the latter can be further subdivided into *deterministic* and *probabilistic* risk assessments. The design differences between these different approaches result in different forms of output.

The type of risk assessment to be used is dependent upon the availability of relevant data and the type of questions to be answered for the risk manager. Qualitative risk assessments evaluate and summarize our knowledge, but does not present a numerical likelihood of an adverse effect. Rather, the risk is evaluated in relative terminology such as “high,” “medium,” “low,” or “negligible”.

Quantitative risk assessments are based on mathematical models, incorporating quantifiable data, and emphasize the likelihood of an adverse health effect (e.g., illness, hospitalization, death). In a quantitative *probabilistic* risk assessment, the uncertainty associated with the risk estimates provides the risk manager with an understanding about the certainty of the estimates. Quantitative MRAs (QMRA) can describe the association of pathogens with typical (generic) food systems (e.g. broiler chicken) or more specific food systems (hot versus cold smoked salmon). Their usefulness in risk management relates to design choices in their development. These choices relate to the specific needs of the risk manager and will determine the level of detail, the segments of the food chain and elements of the food control system taken into account in developing the QMRA. In addition to the needs of risk managers, the availability of pertinent data and modelling techniques will also influence the level of detail taken into consideration.

QMRA can simulate the impact of the food safety control measures on the hazard levels in a food system and the resulting risk level in the population. The various factors in the system can be represented by single numbers (deterministic QMRA) or by distributions of numbers that reflect the variability in the system and/or the uncertainty about the system (probabilistic QMRA). Again the type of quantitative MRA developed depends on the needs of the risk manager as well as the available data and resources.

In the case of a *deterministic QMRA*, single input values are chosen to characterize those values that best represent the factors in the food system. Typical choices are the values that represent the most likely value or, alternatively values that capture a worst case situation. Using most likely values may be sufficient if there is little variability in industry performance, but would be less useful if food safety risks are associated with industry segments that are consistently operating at the extremes of poor performance. Conversely, selecting “worst case” values may be overly stringent for most of the industry if the risks are again associated with the extremes of performance. This will be particularly true if

combining the worst case input values across multiple factors affecting food safety performance. This may lead to unrealistically, overly conservative outputs. On the other hand, using only median or even mean values as point estimates may underestimate risks. Deterministic risk assessment do not provide information on the uncertainty of the risk estimate.

With *probabilistic QMRA*, the input values are distributions that reflect variability and/or uncertainty. The advantage of probabilistic QMRA is that it provides more information about the effect on the risk estimate of the variability and uncertainty associated with the risk assessment inputs. This fuller understanding of key aspects of the risk assessment that is provided by the probabilistic approach gives the risk manager greater confidence that the risk management options/measures/food safety control measures that are selected will achieve the required level of protection. However, probabilistic QMRA provide risk communication and risk management challenges since the decision regarding the level of safety required may need to be expressed as a safe/not safe criterion, i.e. a single number rather than a distribution.

A complete description of the characteristics of deterministic and probabilistic QMRA is available in the FAO/WHO Guidelines on Risk Characterization of Microbiological Hazards in Food<sup>7</sup>.

Current thinking on the validity of risk assessments suggests that the dimensions of validity i.e., is the risk assessment “fit-for-purpose”, should be based on 5 attributes<sup>8</sup>. These are:

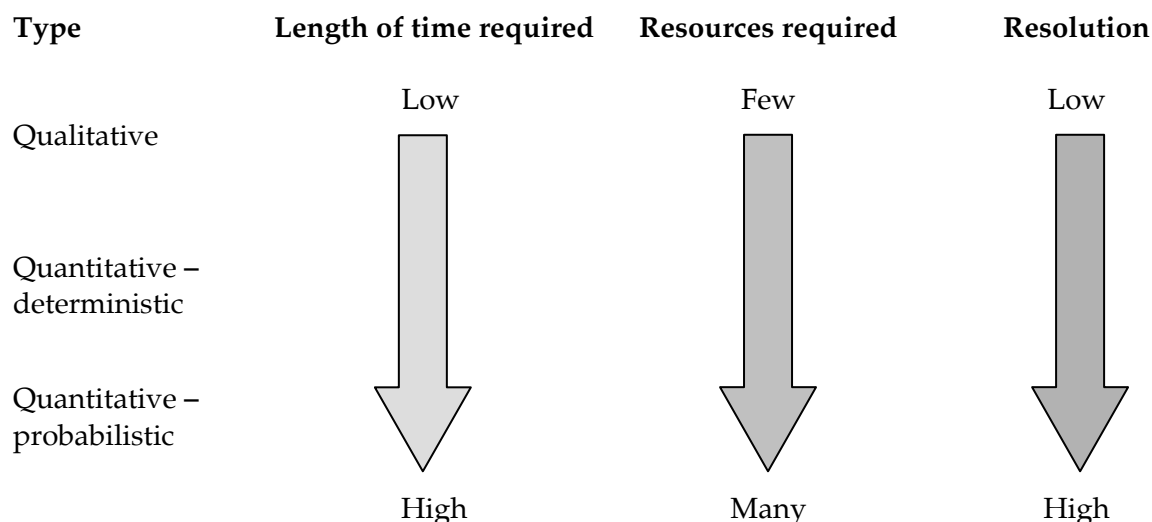
- Quality and transparency of evidence: Collection and assessment of data to be used in the risk assessment.
- Quality of inference: This relates to the probability and, in particular, the level of information that can be associated with probability.
- Transparency of inference (strict and real): This again relates to the probability. ‘Strict’ transparency relates to the ease with which a third party could reproduce the work and ‘real’ transparency relates to whether the target audience of the risk assessment can follow the methods of the risk assessment.
- Timeliness: The time it takes to produce a valid risk assessment; this is often the key factor when deciding which type of risk assessment to undertake.
- Resource requirements: The level of expertise, computer power, etc. needed to produce a risk assessment.

Considering these factors for each of the risk assessment types shows that each type has strengths and weaknesses. In general, in the area of food safety risk assessment, the most common factors considered by the risk managers are: (a) time available; (b) resources requirements and (c) resolution of output. Essentially, a good risk assessment is one that answers the risk question within these constraints – i.e. it is fit for purpose. Figure 2 gives some indication of when a particular type of risk assessment may be more suitable, but it should be noted that even if time and resources are available a qualitative risk assessment is still a valid approach.

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<sup>7</sup> FAO/WHO (in press) Risk characterization of microbiological hazards in foods: Guidelines. Microbiological Risk Assessment Series.

<sup>8</sup> Paoli, G: Dimensions of Validity in Risk Assessment. *In* Background paper to an ILSI/IAFP Workshop on Using Microbiological Risk Assessment in Food Safety Management, Prague, September 2005 (To be published in 2006).



**Figure 2:** Illustration of the factors that influence the decision to undertake a particular type of risk assessment.

### 2.2.2 Considerations regarding the use of MRA

MRAs can be used to describe the food supply chain under investigation and directly relate the effects of different combinations of control measures on the risk to consumers. An important aspect of the usefulness of an MRA in this regard is the confidence that the risk assessor and the risk manager have in the MRA. This confidence can, for instance, relate to the variability in the food supply chains in practice and how well the MRA captures that variability. It can also, for example, relate the uncertainty associated with input values. Both variability and uncertainty carry through into the calculated risk estimate. However, the choice of the type of risk assessment depends on whether these aspects need to be adequately quantified and represented in the outcome of the risk assessment. This choice, and the design of the underlying risk assessment model(s) greatly influences its utility to the risk manager and both the risk assessor and the risk manager should consider this as part of their interactions when defining and commissioning a MRA.

It is important that risk assessors work with the risk managers, so that the risk managers have a very good appreciation of how various risk estimates relate to particular control measure scenarios and understand the impact of variability and uncertainty in the MRA on the risk estimates. This will greatly help risk managers to interpret the outcomes of the risk assessment. It is up to the risk manager then to determine what risk outcome or risk reduction is appropriate and decide which of the scenarios could be taken further to discuss amongst others practical feasibility (involving various stakeholders) and regulatory aspects.

While risk management programs at a national level are developed taking into consideration the overall situation in terms of all of a particular food product consumed in a country, the actual implementation of interventions takes place at the level of individual companies or producers, who may contribute more or less to overall level of risk in a country. This also means that basing a risk management standard on too generic of a MRA could inadequately capture the diversity of industrial entities within a sector and lead to an inadequate consideration of the public health impact.

In some situations, particularly when a farm to fork risk assessment is commissioned, more than one competent authority may be involved (e.g., when a country has primary production regulated independently from the food processing sector). In such cases the MRA can help identify which authority should take the lead in addressing the problem by providing information on which part of the food chain control measures can have the greatest impact. Thus, in such cases, in addition to understanding what the MRA outputs mean, the risk manager needs to have a clear understanding of the scope of the regulatory authority within which the risk management options may be executed. If risk management options need to stretch beyond the existing authority of the risk manager, additional authorities or assistance from other risk managers (e.g., from one or more competent authorities) may need to be pursued. Interaction with these additional authorities should be pursued prior to the development of the MRA including in the elaboration of the risk management questions.

### **2.2.3 Examples of MRA outputs for use in MRM**

Table 1 attempts to identify some of the many potential outputs of MRA and how and where they may contribute to the MRM process. Note that no single risk assessment will necessarily provide all of these outputs. Ultimately the outputs will relate to the initial scope and purpose of the assessment and the subsequent design and development of the MRA to achieve its objective. In addition Table 2 presents a summary of specific risk management options identified during the review of the case studies and describes how MRA contributed to the selection and evaluation of these options.

## **2.3 Epidemiology-based tools**

The development of effective risk-based food safety management that provides the appropriate level of public health protection, should benefit from integrating microbiological risk assessment with other science-based tools and approaches such as those based on epidemiology. As a general principle, epidemiology is a reliable approach to assess the current burden of illness, follow trends over time, and to conduct source attribution<sup>9</sup>.

The most widely used public health indicator to quantify the impact of foodborne illness on a population is the (reported) incidence of illness. Many different countries have established some kind of reporting system, usually based on data from medical microbiological laboratories or on outbreak reports. Such systems capture only a small proportion of the total number of cases. Their advantage is that they are relatively inexpensive to operate and can be sustained on a permanent basis. The burden of foodborne illness is the sum of all cases of illness for all food categories.

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<sup>9</sup> Source attribution: attribution of cases of illness to specific exposure routes including food sources.

**Table 1.** Some examples of the outputs of MRA and their potential use in the MRM process

<i>MRA outputs</i>	<i>Potential use in MRM</i>
Detailed description of the product/pathogen pathway	<ul style="list-style-type: none"> <li>▪ Provides a clear understanding of the food safety issue by taking into consideration all relevant steps of the production process and current control measures, from farm-to-fork.</li> <li>▪ May include a listing of the control measures that can be applied at each of these steps, along with any data regarding the effectiveness of these control measures.</li> <li>▪ Provide a diagrammatic view of the food safety system and the points at which control can be gained or lost.</li> </ul>
Initial and intermediate outputs	<ul style="list-style-type: none"> <li>▪ Provides the opportunity for interaction among risk assessors and risk managers before MRA is completed allowing modifications etc. as necessary.</li> <li>▪ May inform the risk manager about data gaps that could potentially be filled or more completely addressed by the risk manager or research entities.</li> <li>▪ Can provide the risk manager with necessary information in order to take more immediate action to address urgent food safety situations, or to strategize and plan more completely the implementation strategy.</li> <li>▪ Could provide the risk manager with the opportunity to instruct the MRA team that certain risk management questions no longer need to be addressed, and develop new or refined risk management questions.</li> </ul>
Risk ranking	<ul style="list-style-type: none"> <li>▪ A relative risk ranking of various foods impacted by the pathogen of concern.</li> </ul>
Risk estimates	<ul style="list-style-type: none"> <li>▪ Estimates of the risk posed by the pathogen of concern in the food can be expressed in different ways (depending on the level of quantitative data available as inputs to the MRA model), thereby providing the risk manager with different types of information. For example, the risk estimate could be expressed as adverse health end-points(s), including risk per serving, risk per annum, risk per total population, or risk per one or more susceptible or vulnerable sub-groups within the population.</li> </ul>
What-if scenarios	<ul style="list-style-type: none"> <li>▪ Outputs derived from conducting a number of “what-if” scenarios by changing the model input parameters and then measuring the change in the model output predictions. By conducting these types of scenarios, a risk manager can be informed about what may reasonably be expected to happen, such as if a new control requirement is to be applied (Table 2).</li> </ul>
Evaluation of compliance	<ul style="list-style-type: none"> <li>▪ Scenario analysis can be used to assess the importance of the degree of compliance with the proposed risk management option(s) or control measure in achieving the public health goal. In this context, “compliance” refers to the likelihood that the risk management control measure will be adhered to by the appropriate targeted audience (e.g., primary producer, processor, retailer, consumer).</li> <li>▪ The MRA could be designed to model the contribution of compliance to risk in order to provide the risk manager with an understanding about the practicality, feasibility, and effectiveness of the control measure.</li> </ul>
Evaluation of testing regimes (sampling plans)	<ul style="list-style-type: none"> <li>▪ Modelling of testing regimes allows an estimation of the level of risk reduction resulting from the application of several different schemes (this was done for testing schemes for <i>Enterobacter sakazakii</i> in powdered infant formula<sup>10</sup>).</li> </ul>

<sup>10</sup> FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. Microbiological risk assessment series, No 10.

<p>Information on uncertainty and variability around data inputs and / or outputs</p>	<ul style="list-style-type: none"> <li>▪ Characterizes the level and source of uncertainty and variability in the assessment.</li> <li>▪ Reflects the robustness of the data used.</li> <li>▪ Provides the risk manager with an understanding of the impact of the data, approach and assumptions on the output of the MRA.</li> <li>▪ If it indicates that available data are poor it may provide the basis for prioritising research or specific data collection activities.</li> <li>▪ Makes the risk manager aware of any data limitations in developing the MRA.</li> <li>▪ Allows the risk manager to understand how much weight can be put on the outputs of the risk assessment. An unacceptably large uncertainty may lead to a decision to collect further data and re-evaluate risk, rather than initiate an action or intervention.</li> </ul>
<p>Validation, reality check</p>	<ul style="list-style-type: none"> <li>▪ This can be achieved by comparing the output of the risk assessment with independently obtained data and can provide the risk manager with information on how closely the risk assessment reflects reality.</li> </ul>
<p>Sensitivity analysis</p>	<ul style="list-style-type: none"> <li>▪ Sensitivity analysis can be used to evaluate the effects of uncertainty about individual input values or the risk estimates.</li> <li>▪ It can help identify the most important data gaps.</li> <li>▪ It can be used to identify which factors in the model have greatest impact on the risk estimate, leading to suggestions about which potential control measures may have the greatest impact.</li> </ul>
<p>Data gaps</p>	<ul style="list-style-type: none"> <li>▪ Identifies the type and quantity of data that are lacking and the likely impact that has on the risk estimates in order to more completely or reliably provide answers to the questions posed by the risk manager.</li> <li>▪ Facilitates the establishment of priorities for future research.</li> </ul>
<p>Inputs for economic analysis</p>	<ul style="list-style-type: none"> <li>▪ The risk assessment provides information that can be used in the economic quantification of particular risk management interventions. For example economic analysis can use information on human health risk or changes to human health risk and provide an evaluation in monetary terms or healthy life years equivalent.</li> </ul>

**Table 2:** Examples of Risk Management Options that would benefit from the availability of a Microbiological Risk Assessment.

RISK MANAGEMENT (RM) GOALS	RM- OPTIONS <sup>1</sup> AVAILABLE TO ACHIEVE GOALS	EXAMPLES from case studies	ESTIMATED PUBLIC HEALTH BENEFITS	VERIFICATION (Will the RM-option be implemented?)	MONITORING (Will the RM-option be effective?)	REFERENCE (Case studies only ) <sup>2</sup>
Avoid exposure to a specific food	Ban production and/or harvest	No oyster harvest April-September to avoid exposure to <i>Vibrio vulnificus</i>	Risk reduction 74%	Audit by industry Enforcement by inspection by competent authority	Results of auditing Epidemiological data	<b>Case study 5<sup>3</sup>:</b> section 4A
	Ban importation	No example in case studies	Decrease/prevent any increase in illnesses	Audit by industry Enforcement by inspection by competent authority	Epidemiological data	
Reducing consumer exposure to hazards in specific foods	Informing vulnerable consumers (and care-givers) not to eat specific foods	Educate vulnerable consumers not to eat raw oysters	Risk reduction goal 60 %	Surveys	Epidemiological data Consumer focus groups Surveys	<b>Case study 5:</b> section 4D
	Preventing a food from entering the food chain	Preventing table eggs contaminated with <i>Salmonella</i> Enteritidis from entering the market by culling infected breeder flocks of chickens	50% reduction of cases within 3 years	Audit by industry Enforcement by competent authority	Results of auditing Epidemiological data	<b>Case study 6<sup>4</sup>:</b> Section 4.1.2, Table 3, section 4.1.3

RISK MANAGEMENT GOALS	RM- OPTIONS <sup>1)</sup> AVAILABLE TO ACHIEVE GOALS	EXAMPLES from case studies	ESTIMATED PUBLIC HEALTH BENEFITS	VERIFICATION (Will the RM-option be implemented?)	MONITORING (Will the RM-option be effective?)	REFERENCE (Case studies only) <sup>2)</sup>
Control initial levels of hazards in raw ingredients derived from primary production or those ingredients entering the processing environment	Using microbiological criteria to identify and reject unacceptable ingredients or products	<i>Escherichia coli</i> O157:H7 in raw ground beef	Should be assessed	Auditing and verification (microbiological sampling and testing) by industry and competent authority	Epidemiological data Microbiological testing Results of auditing (including control of industry records)	<b>Case Study 3<sup>5)</sup>:</b> section 4.4.2
	Selecting ingredients that have undergone reduction treatment	Common examples, but not in case studies: Irradiation of spices for further use or pasteurization of eggs for mayonnaise production	Should be assessed	Audit by industry Enforcement by competent authority	Results of auditing Epidemiological data	
	Development and implementation or review of current Codes of Practice addressing GAP/ GMP/GHP/HACCP <sup>1)</sup>	Improvement of kitchen hygiene by use of a code of practice to avoid cross-contamination with <i>Campylobacter jejuni</i> from chicken carcasses	Should be assessed	Audit by industry Inspection or auditing by competent authority	Results of auditing Epidemiological data	
Prevent an increase in contamination and the level of a hazard in a food	Reduce additional (re)contamination and growth of pathogens.	Storage of eggs at an environmental temperature at or below 7.2 °C to prevent growth of <i>S. Enteritidis</i>	8-12 % reduction of <i>S. Enteritidis</i> salmonellosis associated with consumption of table eggs	Audit by industry Inspection or auditing by competent authority	Results of auditing Epidemiological data	<b>Case Study 6:</b> section 3.2.2,

RISK MANAGEMENT GOALS	RM- OPTIONS <sup>1)</sup> AVAILABLE TO ACHIEVE GOALS	EXAMPLES from case studies	ESTIMATED PUBLIC HEALTH BENEFITS	VERIFICATION (Will the RM-option be implemented?)	MONITORING (Will the RM-option be effective?)	REFERENCE (Case studies only ) <sup>2</sup>
Reduce level of hazard in a food	Implementation of selected processing operations which eliminates or reduces pathogens	Hot smoking salmon achieves a 7-8 log reduction of the initial level of <i>Listeria monocytogenes</i>	Should be assessed	Audit by industry Inspection or auditing by competent authority	Results of auditing Epidemiological data Validation studies	<b>Case Study 4<sup>7</sup>:</b> section 4,
Remove pathogen from a food	Implementation of processing operations which remove pathogens	Common examples, but not in case studies: Microfiltration and/or centrifugation of milk	Should be assessed	Audit by industry Inspection or auditing by competent authority	Results of auditing Validation studies	
Do nothing (maintain status quo)	Not applicable		Status quo acceptable	Not applicable	Not applicable	

<sup>1</sup> Codes of practices (addressing Good Agriculture Practices (GAP), Good Manufacturing Practices (GMP), GHP and HACCP) in most cases are applicable as a means of achieving the selected risk management option.

<sup>2</sup> Case studies will be published on the FAO and WHO webpages.

<sup>3</sup> Case study 5: *Vibrio vulnificus* in oysters.

<sup>4</sup> Case study 6: *Salmonella* Enteritidis in table eggs.

<sup>5</sup> Case study 3: *Escherichia coli* O157:H7 in fresh raw ground beef.

<sup>6</sup> Case study 7: *Campylobacter jejuni* in poultry.

<sup>7</sup> Case study 4: *Listeria monocytogenes* in smoked fish.

### **2.3.1 Source attribution**

To better control foodborne disease, risk managers require knowledge about the public health impact and relative contribution of possible sources and exposure pathways. The process of defining this relative contribution is often described as “source attribution”. The attribution of cases of human *Salmonella* Enteritidis infection to eggs is an example of source attribution. Source attribution analysis support risk managers in evaluating the need for and/or the effect of food safety interventions and thereby facilitate efficient allocation of resources.

The draft Codex principles and guidelines for the conduct of MRM require relevant epidemiological information to be presented in the risk profile in the preliminary steps of MRM. Source attribution relies on epidemiological and microbiological data collected through surveillance of human illness. Approaches include the analysis of outbreak investigations, analytical epidemiological studies (e.g. case-control studies) and microbial subtyping. The last of these requires data not only from humans but may also require data from animal, plant, food, environmental, and other potential sources. Risk managers have an important role in obtaining these data for instance by establishing monitoring programmes along the food chain.

### **2.3.2 Analysis of outbreak investigations**

Since outbreak investigations may implicate a particular food source, an analysis of these investigations is an approach for source attribution. In some countries, this is the only approach available for source attribution. By analysing data on foodborne disease outbreaks, epidemiologists can evaluate trends and determine the most common food vehicles involved. It is suggested that results from outbreak investigations can, to some extent, can also be used for attributing sources of infection that are not related to outbreaks (sporadic infections), bearing in mind that the relative importance of sources of outbreaks and sporadic cases may differ.

### **2.3.3 Analytical epidemiological studies**

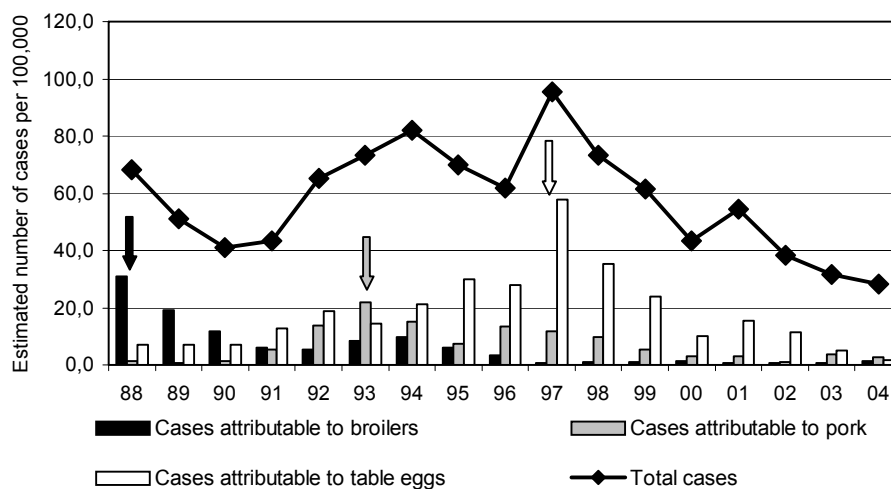
Case-control studies are studies where data on relevant exposures are obtained from case-patients as well as asymptomatic (uninfected) control persons. Well-conducted case-control studies are important sources of information, because it is possible to estimate the relative role of several different food exposures over a large period of time in a representative sample of culture confirmed cases. However, case-control studies have their limitations, including misclassification of the exposure, which may lead to an underestimation of the attributable fractions of several food items. Particularly for common exposures, the statistical power to determine their individual importance may be small. Case-control studies are subject to a number of biases, including recall bias due to memory lapses and possibly selection bias.

### **2.3.4 Microbial subtyping**

Microbial subtyping involves characterization of the pathogen by different pheno- or genotypic typing methods (e.g. serotyping, phage typing, antimicrobial susceptibility testing, pulsed-field gel electrophoresis and sequence-based subtyping). The principle is to compare

subtypes of isolates from animals, food and humans. It is a pre-requisite that some of the dominant subtypes are found almost exclusively in a single source. Such subtypes are regarded as indicators for the human health impact of that particular source, assuming that all human infections with these subtypes originate only from that source. Human infections caused by subtypes found in several sources are then distributed relative to the prevalence of the indicators. This approach requires integrated surveillance of the pathogen in most major food animals, food (including imported food) and humans, providing a collection of representative isolates from the farm-to-fork chain, followed by the use of appropriate discriminatory typing methods.

An example of the microbial subtyping approach to source attribution is demonstrated by annual estimates for the impact of major food and animal sources in human salmonellosis in Denmark (Figure 3). The figure also shows the impact of control measures.



**Figure 3:** Incidence of laboratory-confirmed human *Salmonella* cases attributed to major domestic sources in Denmark. The arrows indicate the year of initiation of control programmes.

## 2.4 Economic analysis (Cost-benefit analysis)

Economic evaluations can be used by the risk manager to weigh which risk management options provide the necessary level of control in relation to the costs and benefits to stakeholders. While this tool is not currently addressed in the draft Codex principles and guidelines for MRM it is being increasingly identified as an important tool for risk managers. This activity is not a function of the MRA, but the MRA can be used to inform this risk management activity. Often a well constructed MRA is the basis for the subsequent economic analysis. In designing a MRA it is a good idea to include an economist in the risk management team so the subsequent data needs for an economic analysis can be included in the MRA.

In undertaking an economic evaluation, a variety of risk management options are generally considered, including doing nothing (e.g. maintaining the status quo). The design features of an economic evaluation, particularly for public health purposes, are well defined by some regulatory authorities (e.g. the Office of Management and Budget in the United States of America, the European Union Commission regulations). Upon completion of the economic evaluation, the risk manager could use such protocols, when available, together with the

other relevant information such as the outcome of the MRA to select the risk management option(s) that provides the desired public health outcome in relation to the cost to society, including the regulated industry.

### 3 ESTABLISHMENT / USE OF METRICS IN THE MRM PROCESS

#### 3.1 Introduction

Agencies responsible for food safety have traditionally found it beneficial to be able to articulate to food industry the degree of stringency that needs to be achieved at one or more specific steps along the food chain in order to deliver a final product that meets expectations in relation to consumer safety. The expected stringency can be communicated in different ways such as the stipulation of manufacturing requirements, for example through the use of process criteria or product testing (e.g., microbiological criteria), to distinguish acceptable and non-acceptable products. These limits have been traditionally established through expert advice and related to a certain level of stringency that was considered to be adequate either at a specific step in, or the end of the food chain. However, with the recent advances in microbiological risk assessment techniques, national governments, international intergovernmental agencies (e.g., Codex Alimentarius), and industry have correctly realized that it is possible to more transparently and objectively relate the establishment of such limits to the intended public health outcome within a risk-based food safety management system. The draft Codex principles and guidelines for the conduct of MRM (Annex VI) proposes to use the terms FSO, PO and PC (see text box for definitions) to communicate the limits required at specific points in food supply chains in an explicit way to the affected food industry. For the purposes of this document these are considered to be and referred to as *intermediate targets*.

Three new “intermediate” targets are defined by Codex (Procedural manual, 15<sup>th</sup> ed.), as follows:

- Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).
- Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.
- Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

An important aspect of the establishment of such targets is the possibility to link them to public health outcomes and in that way be able to illustrate the relationship between control measures and ALOP or public health goals. In this context it is critical that there is a clear understanding of what an ALOP or public health goal actually is and the differences between these terms and their purpose. During the initial discussions the meeting noted that these terms are sometimes incorrectly used interchangeably. Using the case studies and the lessons learned in their development together with the working group discussions, this section attempts to clarify the role of public health goals and ALOP as well as describe the current status with regard to the use of MRA in the development of risk management targets and in establishing and evaluating control measures.

### 3.2 Public health status and public health goals

Public health goals are set to inspire action to improve the public health status and reduce disease burden. Public health goals will usually be set by government or public health bodies, with a varying degree of input from stakeholders, and imply some consideration of the current health status and disease burden (in the population as a whole or in vulnerable sub-populations). In setting goals, consideration should also be given to feasibility, possible control measures to achieve the goal, and how achievement of the goal is to be measured. An unrealistic goal that is not grounded in a realistic assessment of the ability to achieve the goal, may be counterproductive. A goal may be simply the maintenance of current levels of health protection when evaluating the impact of changes in food production systems and technologies, modifying food trading, quality or safety policies, and also when judging the equivalence of different measures in different countries.

Expression of public health goals may range from the general to the specific, depending upon the level of source attribution. For example, a very general public health goal would be to reduce the incidence of human *Salmonella* infections, while a more specific goal would be to reduce the incidence of human *Salmonella* Enteritidis infections. However, to be actionable the degree of specificity and attribution would likely have to be even more specific, e.g., reduce the incidence of human cases of *Salmonella* Enteritidis associated with consumption of eggs. Goals may be set either in absolute terms (e.g. number of cases per 100,000 population) or in terms of relative improvement (e.g. a percentage reduction in the number of cases).

When a public health goal is established as a risk reduction target, a well designed MRA can establish the magnitude of risk reduction that would need to be achieved by changes in control measures in order for the public health goal to become the ALOP. Typically, different scenarios of choices of control measures are considered during an MRA and a range of associated risk outcomes is calculated. It is good practice to consider the impact of likely variability in performance or compliance (see section 3.4.4) in these scenarios as well the possible constraints in the choice of control measures for the given situation.

Public health status is a measure of the current health situation in the population and can also be expressed in general or specific terms. Consequently the public health status may be used as a basis from which to establish future public health goals or alternatively, as a measure of the effectiveness of risk management actions. When these concepts are applied, an appreciation of the current capability of a country's public health surveillance to measure the incidence of disease and its attached uncertainty, may have to be considered, particularly if attainment of these goals are going to lead to decisions regarding future food safety risk management decisions.

### 3.3 Appropriate Level of Protection (ALOP)

A particular expression of the current public health status is the Appropriate Level of Protection (ALOP). This concept originated from the SPS Agreement, where it is defined as follows:

*“The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”<sup>11</sup>*

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<sup>11</sup> The Agreement on the Application of Sanitary and Phytosanitary Measures. WTO 1994.

An ALOP is an expression of the level of protection achieved in relation to food safety control measures in place at the current time. In contrast to a public health goal an ALOP is not the formulation of some future objective. However, because the currently achieved public health status may change (for example, new technologies may change the level of a contaminant in a food), an ALOP may be revised over time. Further guidance in this area in the context of the SPS agreement have been provided by WTO.<sup>12</sup>

ALOPs may be general or specific, this depends on a number of factors, for example the extent to which illness can be attributed to a specific food commodity. An example of a general ALOP could be the current level of *Salmonella* infections in a country (e.g. the incidence of salmonellosis in Finland and Sweden when they joined the European Union). An example of a specific ALOP was the background level of cryptosporidiosis attributed to drinking water in the USA, and this was used as a basis for establishing levels of treatment for drinking water.

An appropriately designed MRA can be used to quantify the impact of the current food control system on risk and provide a numerical description of the level of protection which it is achieving i.e. the current ALOP. Furthermore MRA can be used to assess the risk mitigation likely to be achieved by the implementation of specific control measures and compare this to the ALOP. If such measures would have a negative impact on ALOP then they would have to be modified or replaced so that the ALOP would not be compromised. As well as providing a means to evaluate the impact of changes in processes or control measures in the domestic setting on ALOP, MRA can also be used as a means of evaluating the impact of imported food on ALOP.

### 3.4 Using MRA to establish and evaluate metrics

Food safety management systems exert their control through the control measures that are put in place. The stringency of these control measures will determine the overall level of control that will be achieved by the food safety system. For example, in primary production of raw meat, control measures would be focussed on the selection of animals before slaughter or in the phases thereafter, at hygiene during slaughtering, or the maintenance of the cold chain through to retail sale. For food processing industries, typical control measures are physical (e.g. heating, cooling, aseptic filling provisions), chemical (e.g. preservatives, pH,  $a_w$ ), operational (e.g. good hygienic practice, inspection), etc. For some control measures, process criteria and product criteria can be useful as operational parameters. Process criteria might, for instance, specify the time and temperature needed for a heat treatment to achieve a particular inactivation of possible pathogens. Similarly, product criteria might, for example, define the type and amount of acid to be added to a food product and the pH of the food product needed to prevent or minimise growth of a pathogen.

The meeting considered that the role of MRA in food safety risk management was multifaceted. While recognizing that an important focus of the meeting was the use of MRA in the establishment of intermediate targets, MRA as a tool is not limited in its application to this aspect only. Therefore, in addition the meeting sought to outline the range of application of MRA in risk management including its *direct application* to the selection and evaluation of control measures and its application in the verification of compliance.

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<sup>12</sup> Guidelines to further the practical implementation of article 5.5.WTO Committee on Sanitary and Phytosanitary Measures G/SPS/15, 18 July 2000.

### 3.4.1 Using MRA in the selection/evaluation of intermediate targets

#### **Turning intermediate targets into operational standards**

The definitions of FSO, PO and PC provide a conceptual framework for the establishment of intermediate targets that more specifically inform day-to-day risk management than targets at the level of public health could do. They are not designed to be actively controlled and verified in all cases where they might be used, but rather are targets from which to derive appropriate operational standards that can be controlled and verified.

The six case studies provided practical examples of how different groups might approach the task of utilising intermediate targets such as PO or PC to address the risk of food-borne disease. However, experience in practice with using intermediate targets in this way is very limited and there is not a strong practical basis on which to judge the practical utility of this approach.

A common finding of all six case studies was that, while an FSO may be a useful concept for translating control measures, up to and including those at the level of the consumer, into public health outcomes, PO and PC are more likely to be the metrics used for establishing the stringency of a food safety system. An important reason for this is that PO and PC can be utilised at points in the food supply chain where control measures can be implemented and verified, through the implementation of appropriate microbiological criteria, processing criteria and product criteria.

#### **General considerations and challenges in the application of deterministic and probabilistic risk assessment approaches in the establishment of intermediate targets**

Evaluation of the case studies highlighted some potential pitfalls that could be encountered in quantifying the linkage between traditional criteria and the associated control measures, or between intermediate risk management targets and the risk to consumers. These pitfalls relate in particular to the way in which different types of risk assessment may be used in the establishment of intermediate targets. Substantial discussion was devoted to comparing the application of deterministic versus probabilistic risk assessment approaches, as described in section 2.2.1.

It was generally considered that the MRM task is operationally simpler with a deterministic approach, due to the less complex mathematics underlying that type of model. However, this simplicity comes at a cost regarding accuracy and insights into uncertainty. Furthermore, there are several problems that can arise from the arbitrary selection of the degree of confidence required as part of the criteria for making a decision. Following a deterministic approach, a decision must be reached concerning what fraction (portion) of all food product marketed should comply with an intermediate target and this decision should be informed by knowledge of the consequences of allowing a certain proportion of the food which does not meet the criteria into the food chain. For example, if a PO were selected on the basis of its being the most likely value at a specified step in the food chain, then many values would actually exceed this PO value. This can be overcome by selecting a more stringent value, e.g. one that would require all food products concerned to achieve the PO with for instance a 95% or greater confidence limit. In the latter case a situation may arise where the PO value becomes overly conservative. It is worth noting that this is not a new concern; a limiting characteristic for almost any deterministic model is its propensity to generate an overly conservative risk estimate. This is one of the primary reasons for the emphasis on the use of

probabilistic models, whenever feasible. The meeting noted in its consideration of deterministic risk assessments that it was not always clear why in some cases a worst-case value was chosen for one or more of the factors contributing to risk while for others less stringent values were selected.

For these reasons, a probabilistic approach to modelling would in principle offer the best opportunity for operationalizing intermediate targets and would provide the best insight into the uncertainty underlying the risk assessment. However, it was also recognized that the reliance on probabilistic approaches represents a significant challenge regarding risk communication. For instance, this relates to the ability to effectively communicate the modelling and the evaluation of possible intermediate targets to risk managers and other interested parties.

One of the advantages of a properly designed deterministic model is the ability to move forwards and backwards in the model to, for example, determine possible values for a PO and the best point in the chain for this PO, considering the hazard dynamics at earlier or later steps in the food chain. This is not so easy with probabilistic models, where there was general agreement that one could not typically “back calculate” starting at the FSO or a PO to determine what a PO earlier in the food chain would need to be to ensure achievement of the specific level of control. This reflects the fact that it is not possible to determine in a reverse manner the characteristics of multiple distributions associated with earlier steps from the resulting distribution later in the food safety system. This does not mean that probabilistic approaches to risk assessment are not suitable to establish intermediate targets. An adequate procedure would be to estimate the likely value of the earlier PO and then solve the MRA model in an iterative manner until the required value of the later PO and the ultimate target for the risk at population level (ALOP or risk reduction) are achieved at the appropriate confidence level.

### **3.4.2 Direct use of MRA in the selection / evaluation of control measures**

A risk-based review of a food safety system associated with the food safety issue of concern can provide the risk manager with new understanding about the food safety issue and the potential ways it can be influenced along the farm-to-fork continuum. If sufficient data are available and the MRA is appropriately designed, MRA models allow a quantitative evaluation and comparison of the effects of different control measures on public health risk to consumers (i.e., risk per servings) or risk to a country (i.e., risk per annum) on an industry wide basis. For example, one of the case studies presented at the consultation evaluated the potential impact of using flock testing as a means determining how poultry should be treated to mitigate the risk of campylobacteriosis in a human population due to poultry consumption. Through incorporation of appropriate mathematical expressions of the microbiological sampling plans being considered, the model allowed evaluation of the relative risk reductions consequent to flock testing schemes and the impact of consequential product segregation.

The recently established risk assessment model for *Enterobacter sakazakii* in powdered infant formulae<sup>13</sup> included a mathematical means for calculating the relative public health risk consequent to a range of possible microbiological criteria which were each based on different

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<sup>13</sup> FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. Meeting report. Microbiological Risk Assessment Series no. 10.

microbiological sampling plans. This allowed a comparison of the likely impact that particular lot-by-lot testing programs would have on the relative risk in the population. The use of “what-if scenarios” for various control measures in risk assessments has already proven to be an effective means of examining different risk management options, allowing the risk manager to consider potential interventions in a new way. By evaluating them in the risk model for predicted impact on risk i.e. the degree of risk reduction, the risk manager can begin formulating which of the potential parameters seem practical and feasible to implement, if any. Selected options are then considered in regard to other factors.

Table 3 provides an example of how direct use of a risk assessment by the risk manager, considering a range of potential control measures for *Vibrio vulnificus* in oysters, can potentially assist in the reduction of consumer risk.

**Table 3:** Impact of possible control measures on the level of *Vibrio vulnificus* contamination of oysters and subsequent risk (based on consumption of oysters in the USA).

Oyster production	Post harvest handling	Post harvest processing (PHP)	Oyster consumption	FSO	RISK (mean no. cases/annum)
Harvest all year	No change <sup>1</sup>	No change	No change	Not established <sup>2</sup>	32.4 <sup>3</sup>
Harvest only Oct-Jun	No change	No change	No change	Not established	20.2
Harvest all year	Rapid chilling (<1 hour on ice)	No change	No change	Not established	16.2
Harvest only Oct-Mar	No change	No change	No change	Not established	8.5
Harvest all year	No change	<300/gram	No change	<300/gram <sup>4</sup>	7.7
Harvest only Oct-Mar	Rapid chilling (<1 hour on ice)	No change	No change	Not established	4.3
Harvest limited to seawater <20°C	No change	No change	No change	Not established	1.2
Harvest all year	No change	<30/gram	No change	<30/gram <sup>4</sup>	1.2
Harvest all year	No change	<3/gram	No change	<3/gram <sup>4</sup>	0.16

<sup>1</sup> No change indicates that practices and *V. vulnificus* levels would be the same as those described in the FAO/WHO *V. vulnificus* risk assessment and vary by season.

<sup>2</sup> No FSO was established because it assumes that *V. vulnificus* levels would be based on the exposure levels described in the FAO/WHO *V. vulnificus* risk assessment.

<sup>3</sup> Mean number of cases is based on data in the FAO/WHO *V. vulnificus* risk assessment.

<sup>4</sup> Assumed no growth after PHP.

This discussion on the direct use of MRA in the selection/evaluation of control measures seems to indicate that this mode of application of MRA for selection and/or evaluation of control measures is a useful tool in risk management.

### 3.4.3 Monitoring to verify effectiveness of control measures

Monitoring of specific steps in a food production system to verify the effectiveness of an individual food safety measure is considered to be part of the implementation of food safety measures. Review of risk management strategies and food safety measures is necessary to assess whether or not they as a whole, or one in particular is successful in achieving the desired results and appropriately contributing to consumer protection. This step benefits from the use of a range of tools including MRA and epidemiology based tools as described in section 2. Monitoring and review can be considered tools in themselves to facilitate the risk management process and identify whether an ALOP or public health goal is achieved. The actual degree of public health protection achieved is also dependent on the frequency at which this level of control is actually achieved, i.e. degree of compliance in a country as a whole. The role of these tools in compliance is addressed in section 3.4.4.

Risk management options selected for affecting an impact on public health, whether a regulatory change is necessitated or not, is enhanced when an implementation strategy is designed to measure the effectiveness of the risk management option. In some cases, if public health is not enhanced as a consequence of the risk management action, the risk management option needs to be modified, including the enforcement strategy. Enhanced enforcement or education may resolve the problem and the MRA may be reassessed when public health is not impacted as desired.

### 3.4.4 Using MRA in verifying compliance

When food safety control measures are adequately implemented and achieve the performance projected, it is expected that the target level of protection will be met. Where POs and PCs are used as intermediate targets to articulate the degree of control over a hazard at a specified step in the food chain, again, whether the expected level of control is achieved depends on how well the food safety control measures derived from them have been implemented and perform. The likely impact of choosing different food safety control measures or setting different PO or PC values on the resulting risk in the population can be estimated if an appropriately designed MRA is available. However, the actual degree of public health protection achieved is also dependent on the frequency at which this level of control is actually achieved, i.e. *degree of compliance* in a country as a whole. A country could establish a highly stringent PO or PC, but if that limit is met at a frequency of 1%, the overall impact of the PO or PC could be minimal.

For example, the “FAO/WHO Microbiological Risk Assessment on *Listeria monocytogenes* in Ready-to-Eat Foods” (2004) explored the potential level of public health protection expected from two PO values (0.04 and 100 CFU/g) and the observed incidence of disease. The actual incidence of disease was substantially higher than the level predicted if either PO was always achieved. If it is assumed that the QMRA covered all relevant factors adequately, (e.g., no cross contamination, particularly between products that do support growth of the pathogen versus products that do not; fully informed and documented attribution of illness from all food sources), then the higher disease incidence probably is explained by a significant degree of non-compliance to a one or more relevant control measures.

The availability of an appropriately designed QMRA can be a highly effective tool for exploring the impact of compliance. In particular, the development of scenario analysis that examines different frequencies and degrees on non-compliance to a microbiological limit, or

another relevant control measure, can provide the risk managers with advice on how attainment of a public health goal or an ALOP could be confounded. These estimates, in turn, can be used to evaluate the degree of verification that will be needed to assure adequate compliance

Another aspect of compliance that was explored by the “FAO/WHO Microbiological Risk Assessment on *Listeria monocytogenes* in Ready-to-Eat Foods” was the use of a MRA to explore the stringency of a PO versus the likelihood of compliance. Using appropriately designed scenario analyses, this study indicated the possibility that a less stringent PO that allowed easier verification (and thus could be used to achieve an increased level of compliance) could lead to a decrease in the incidence of disease. However the practicality and feasibility of implementing such a food safety control should be considered by the risk manager.

### **Approaches for verifying compliance**

When a PO or PC has been established to communicate the level of stringency expected at a specific step in the food chain, it should be verifiable whenever possible. This could be verification of the effect of (one or more) control measures. Ideally, the means for verifying compliance would be established at the same time and the confidence that needs to be achieved in the verification approach be considered in the establishment of the public health target.

Food control systems need to undergo systematic evaluations to verify that they are functioning as intended. This verification activity is done by industry, or by a competent authority as part of a formal auditing program. Ideally, quantitative means would be used as the basis of verification. There may be many direct and indirect means to conduct verification, including chemical or physical characteristics of the food, processing records or raw material data. There may be instances where qualitative approaches such as inspection of farms and factories for adherence to GAPs and GHPs can be indicative of an operation achieving a specified level of control. Microbiological testing is regularly a component for verifying compliance against a particular control measure, a microbiological limit such as a PO, or even a complete food safety system. However, when used in this manner microbiological testing is often conceptually different than the traditional microbiological testing that segregates acceptable and unacceptable lots based on intensive sampling of individual lots of foods. Instead, periodic sampling of multiple lots is performed to establish trends, so that corrective actions can be undertaken when the testing indicates a deviation of the intended level of control. Both types of microbiological testing should be based on sampling protocols and methodology that together provide the level of sensitivity appropriate for the evaluation of the degree of compliance required for the measure(s) considered. The meeting noted that without careful differentiation of these two types of microbiological testing there is potential for ongoing confusion and that international guidance on distinguishing these may be useful.

The availability of a QMRA and the ability to perform scenario and sensitivity analyses can provide the risk manager with insights into viable verification approaches. In particular, it can provide information on the levels and frequency of the hazards that are likely to occur. This is important information regarding the selection of appropriate sampling and analytical protocols. Based on knowledge about the level of confidence underlying the verification program, these tools can inform the risk manager about the impact of an expected frequency of non-compliant units to the level of protection achieved.

## 4 CONCLUSIONS AND RECOMMENDATIONS

### 4.1 Conclusions

It was concluded that:

Microbiological risk assessment has a valuable role to play in food safety risk management. It can be used alone or in combination with other tools such as epidemiology based tools or economic analysis. Epidemiology based tools have an important role to play in MRM, particularly in preliminary risk management activities and monitoring and review and there is a need to use epidemiology to its full utility.

There are different types of quantitative microbiological risk assessment (QMRA) (deterministic and probabilistic) and these tools are highly desirable, facilitating the establishment of a quantitative relationship between exposure through consumption of contaminated food intake and its health impact (illness). MRA also facilitates the evaluation of the effectiveness and feasibility of possible control measures.

An important aspect of linking control measures along the food chain to impact on consumer health is the definition of ALOP and public health goals. The meeting noted that these terms are often wrongly used interchangeably and highlighted the importance of understanding ALOP as it is defined in the SPS agreement as the currently achieved level of protection. A public health goal can be both a current or future target and cannot be used to impose stricter measures on imported foods.

The direct use of QMRA implies that the effect of mitigation options is simulated in a model to estimate the effects of possible control measures on public health and to evaluate if a public health target will be met in the future or whether an ALOP is being currently met. This approach has already proven to be an effective means of examining different risk management options.

The indirect use of QMRA facilitates the establishment of targets or metrics at various points along the food chain. In some situations the direct use of QMRA may be limited in its application or restrictive in terms of control measures, for example in managing the safety of foods where there is diversity in the way these foods are manufactured and where there are multiple approaches to managing risks. In such cases intermediate targets, from which relevant food safety controls can be derived, are desirable for risk managers and industry to define the necessary level of hazard control at specific steps in the food chain.

When PO or PC can be set at different steps in a food chain or when different values for them are considered, the QMRA can be used to evaluate how well various alternatives contribute to achieving the required level of protection. PO and PC can be helpful guides, but they are not the ultimate goals.

The case studies provided examples of multiple approaches for establishing intermediate targets using MRA. Though all examples provided a transparent presentation of how conclusions were reached, some case studies identified difficulties in applying the present Codex definitions of FSO, PO and PC. Following an extensive discussion on the application of FSO, PO and PC as they are defined by Codex and the role of MRA in establishing these, the meeting concluded that, particularly for probabilistic MRA, there was a need for further

elaboration. Specifically, a number of the meeting participants considered the word “maximum” in the definition of the PO to be difficult to apply within a probabilistic approach as it needs to be viewed as a limit to the level of a hazard at a certain step in the food chain. This limit is to be achieved with a certain degree of confidence. The word “effect” in the definition of the PC also needs to be viewed as a level of control to be achieved with a specified degree of confidence. Choices of the degree of confidence are up to the risk manager. While there were some participants who felt that the definitions are flexible enough to be operationally defined, there is no experience with this, so the meeting was unable to provide practical advice as to how to proceed, but concluded that it was an area which should be further addressed in the immediate future.

The likely compliance to limits and other control measures can greatly impact on the level of public health protection achieved by control measures and must be considered in the implementation of a food safety control program. With regard to the role of microbiological testing in verifying compliance the meeting noted that when used in this manner it is often conceptually different than the traditional microbiological testing and concluded that guidance in this area would also be useful to minimise and prevent any confusion between these two uses of microbiological testing.

## **4.2 Recommendations**

In the course of the discussions the meeting identified a number of issues could not be addressed in full within the available timeframe but felt were pertinent to the development of practical risk management strategies. To this end the meeting made the following recommendations.

1. Governments should invest resources in strengthening food safety programmes, to collect, interpret and use available data, particularly in the area of monitoring and surveillance. They should promote inter-sectorial (veterinary, public health and food-related disciplines) and inter-disciplinary (e.g. microbiology, epidemiology and risk assessment) collaboration.
2. Codex and member countries should make it a priority to improve the synergy between quantitative risk assessment approaches and quantitative epidemiological analysis (including source attribution) to further improve risk-based food safety management approaches and to better inform the development of public health goals.
3. Governments, the scientific community and the food industry should strengthen technical co-operation and capacity building to enhance risk assessment and epidemiological capabilities at national and international level with the assistance of FAO and WHO.
4. The direct use of MRA should continue to be applied as a practical means to establish food safety control measures. While recognizing that there is still significant work needed from the technical side to practically use MRA, and specifically probabilistic MRA, in the development of intermediate targets, work on this issue should be continued at the international level. One of the particular challenges to be addressed is related to the use of the term “maximum” in the current definitions of FSO, PO and PC which may be considered as not very compatible with what is currently accepted as the outputs of probabilistic risk assessment. While opinions on this issue varied it was

recommended that further discussions are needed to consider how this discrepancy could be resolved.

5. Evaluations should be undertaken in the immediate future to provide greater insight into the means for linking the risk management tools, such as FSO/PO/PC, to the level of public health protection and facilitate the provision of practical guidance.
6. Having noted from practical experience that there is more emphasis on a role of PO/PC as intermediate targets from which food safety control measures are derived than on FSO, it is recommended to CCFH to consider amending the existing MRM document to reflect this new emphasis.
7. FAO/WHO should consider providing practical guidelines in distinguishing the use of microbiological testing<sup>14</sup> as a control measure versus its use in verifying the performance of food safety systems.
8. Ongoing development of practical plain language guidance on how to implement risk management options should remain a priority for FAO, WHO and Codex. Such guidance facilitates consumer protection and trade.

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<sup>14</sup> The current definition of microbiological criteria in Codex is limited to lot testing at port of entry to segregate acceptable from non-acceptable product based on a microbiological limit. This is however only one way in which microbiological criteria can be used; there are other ways but confusion exists about how microbiological criteria are used in reality in practical settings. Therefore there is a need to clarify this issue.

## 5 ONGOING AND FUTURE WORK

As noted in section 4 the expert meeting concluded that in certain cases, the FSO concept is of limited practical use and that most discussions will focus on the PO and PC concepts. Applying the definitions of PO and PC to the results of a deterministic risk assessment is straightforward as such models will produce single (point) estimates of risk and of pathogen occurrence along the food chain. The construction of deterministic models does imply, however, that all parameters in the model are represented by point estimates, while they may reflect factors that are highly variable in reality. Incorporation of variability may be necessary to arrive at proper risk estimates. Furthermore, there may be uncertainty about many factors included in the model. In order to account for the effects of variability and uncertainty most QMRA models are probabilistic in nature rather than deterministic. Application of the PO and PC concepts in a probabilistic framework is more complicated as at each point in the food chain, the distribution of hazard concentrations and their dynamics has to be taken into account. In the limited time available, the Expert Meeting was not able to provide recommendations on the application of the intermediate targets in a probabilistic framework. There a workshop will be implemented in November 2006 to take up this challenge.

The workshop will:

*“Provide a technical basis for consideration of variability and uncertainty when using microbiological risk assessment models to articulate Performance Objectives and Performance Criteria that establish the required level of hazard control along the food chain in relation to the Appropriate Level of Protection.”*

The workshop will convene a small group of specialists in microbiological risk assessment and risk management, who will examine the articulation of POs and PCs in both a deterministic and a probabilistic framework in more detail. They will base their work on a generic microbiological risk assessment model<sup>15</sup> as well as two or three case studies, selected from the background documents for the Kiel Expert Meeting and other FAO/WHO risk assessment work such as that on *Enterobacter sakazakii* in powdered infant formula. At least one member of the teams that developed the models for these case studies will be present so that models are available and can be used. Participants will generate and discuss possible approaches in electronic discussions and teleconferences before the meeting. All suggestions will be collated in one document by the organizers. The meeting will begin with a discussion of strengths and weaknesses of proposed approaches, possibly generating additional ideas. Then, strategies to implement PO and PC definitions in the QMRA models will be developed and tested. Successful strategies will then be defined more precisely and attention will be focused on how risk managers in government and industry can set POs and PCs and how to verify if industry meets these targets. Based on the outcome of the technical discussions the meeting will consider the current definitions for the intermediate targets in terms of their ability to describe what is technically feasible.

The output of the meeting will be a report to FAO and WHO, to be used in the follow-up to the Kiel meeting and as part of their programme of work to provide scientific advice to countries and to support the activities of Codex. Technical results of the workshop will, if possible, be the basis for a peer-reviewed paper.

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<sup>15</sup> In preparing this workshop it was agreed to attempt the development of a generalized MRA-MRM scheme, which could be useful to examine the issues at stake, but also could serve a key role in future practical guidance.

APPENDIX VII from the report of the 37th session of the Codex  
Committee on Food Hygiene (ALINORM 05/28/13)

**NEEDS OF CCFH FOR THE PROVISION OF SCIENTIFIC ADVICE BY FAO/WHO  
ON THE APPLICATION OF RISK ASSESSMENT TO RISK MANAGEMENT**

## **2.1 Introduction**

During the course of the past ten years, the Codex Committee on Food Hygiene (CCFH) has been developing and embracing a risk analysis framework in which it would undertake and carry out its work related to the provision of practical guidance and standards for control of microbiological hazards in foods. This has included the development of new concepts and approaches, such as the application of food safety objectives (FSOs), performance objectives (POs), and performance criteria (PCs), in order to relate public health goals to the level of stringency required for food safety control measures and systems. These new parameters could then be translated into more traditional measures of food safety control stringency such as process criteria, product criteria, and microbiological criteria. However, it has become evident that during the conduct of current projects within CCFH, particularly in relation to the development of the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CX/FH 05/37/6, 2005), and the *Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-eat Foods* (CX/FH 05/37/05), that the work of CCFH would be greatly simplified if there was a single FAO/WHO JEMRA document that could serve as a reference for the concepts, techniques and practical examples of how these new metrics can be determined and interrelated.

At the 37<sup>th</sup> Session of the Codex Committee on Food Hygiene, the FAO/WHO reported on plans to conduct during 2005 a consultation on “Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs” (CX/FH 05/37/9). The FAO/WHO proposed that such a consultation be undertaken to address the needs of Codex and member countries. As a means to ensure that the consultation provides information useful to current and future work of CCFH, FAO/WHO requested that CCFH articulate areas of interest that be could addressed as part of the broad goals of the consultation.

### **Purpose**

The purpose of this document is to formally request that FAO/WHO develop, within the framework of ad hoc expert consultations, scientific advice on concepts, methods, and practical examples of (1) how POs and PCs can be related to established public health goals and/or FSOs, and how POs and PCs can, in turn, be translated into more traditional measures of food safety system stringency such as process criteria, product criteria, and microbiological criteria. The ultimate goal of this request would be the availability of a reference document that provides a means for CCFH to address its risk analysis responsibilities, and that ideally could be cited as the explanatory text for the tools that CCFH and countries could use to reach decisions related to these risk management measures. In developing the following terms of reference, the drafters have been particularly cognizant of the current and future needs to relate available risk assessments to the risk management work currently underway in CCFH, including the “*Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*,” the “*Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes*,” the “*Discussion Paper on the Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of Salmonella spp.*”

*in Poultry,” the “Discussion Paper on the Guidelines for the application of the General Principles of Food Hygiene to the Risk Based Control of Enterohemorrhagic Escherichia coli in Ground Beef and Fermented Sausages,” the “Discussion Paper on the Guidelines for Risk Management Options for Campylobacter in Broiler Chickens,” and the “Risk Profile for Vibrio spp. in Seafood.”*

## **2.2 Background**

Previous international expert consultations and the development of risk management frameworks by both CCFH and individual member countries have made significant progress on the development of a general framework based on risk analysis for linking public health goals for control of foodborne disease with the degree of stringency required of food safety measures to achieve those goals. This involves a process using risk assessment techniques to establish the relationship between incidence and severity of disease and the frequency and extent of contamination, i.e. establishment of a FSO. From this relationship and knowledge of the dynamics of pathogen growth, survival, and inactivation, the framework calls for the establishment of scientifically defensible POs and PCs at specific points within the food chain. A major limitation in translating FSOs to POs and PCs is the clear articulation of practical concepts and methods by which the variability and uncertainty identified in the assessment of risk can be evaluated and considered in the decision making process. Practical guidance on how to establish a PO or PC based on a FSO is critical to advancing the application of the microbiological risk management principles being developed by CCFH.

The risk management principles currently being developed within CCFH have also highlighted the desirability of using POs and/or PCs to serve as the basis for more scientifically establishing traditional control measures. These include microbiological criteria, product criteria, and process criteria that are employed to establish the level of control required and verifying that that level of control is achieved. However, there is currently limited practical guidance available on how to interrelate these two classes of food control measures (i.e., PO/PC and microbiological criteria/process criteria/product criteria), particularly in relation to sampling and analytical requirements.

While the general framework has been established, there have been few attempts to actually use it. Thus, CCFH and its members countries and international organizations are still not fully cognizant of the details that would have to be addressed in successfully developing a risk analysis based system wherein public health goals define the criteria used to establish the required level of food safety stringency.

## **2.3 Questions for Consideration**

The overarching questions that should be addressed by the consultation are what are the means and methods for achieving the following goals and what are the limitations associated with such a risk analysis based approach?

- ◆ Establish the context of the FSO/PO concept as a part of a risk management option in relation to the application of a risk based approach
- Establish a FSO that is based on different expressions of ALOP.
- Establish one or more POs at specified points along the food chain that can be related to a FSO,
- Derive, when appropriate, a PC based on an established PO for a specified site along the food chain,
- Derive metrics for food safety stringency (e.g., microbiological criteria, product criteria, process criteria) that can be used to verify that a PO is being met, and
- Assess the impact that compliance to these metrics has on the ability to achieve the public health goals and the stringency and verification required of the system.

In considering these questions, the consultation should provide practical advice and techniques for establishing one or more of the metrics above, when one or more of the metrics “upstream or downstream in the food chain” has not been determined (e.g., establishment of an FSO without an ALOP, establishment of a PO without a FSO and/or ALOP). The consultation should also provide clear advice on the limitations associated with this approach and additional approaches where it is not possible to apply the FSO/PO concept.

In addressing each of these methodological areas, the consultation should provide advice and recommended methods for addressing the diversity that is likely to occur within the food industry in the ingredient sources, manufacturing technologies, marketing strategies, and consumption profiles. In addition, the consultation should provide clear guidance on strategies for verifying that the different metrics are being met, including articulation of methods for assessing the “statistical confidence” for verification strategies. The consultation should provide specific recommendations regarding the types and extent of data that will be needed to deal adequately with the uncertainty and variability associated with food products, particularly those in international trade. Likewise, the consultation should provide specific advice on how to calculate the statistical confidence of strategies for verifying the effectiveness of food control systems.

The development of well articulated realistic examples of how these concepts and techniques can be applied is critical to CCFH being able to adopt a risk analysis approach to its work. There is a wide range of food each with its unique characteristics and hazards. Likewise, there are diverse sites along the food chain where foods can be become contaminated. Thus, a single example is likely to be insufficient to adequately describe the different approaches that may be required to fully consider the subject matter. Accordingly, the consultation is requested to consider the four product/pathogen pairs listed below. These have been selected to provide examples to include different sites of contamination (e.g., post-processing, primary production, during preparation), modes of disease (e.g., infection of general population, infection of specific susceptible populations, intoxication), potential mitigations (e.g., primary production, processing, marketing), and likely sites for the establishment of POs (i.e., primary production, manufacturing, marketing, and preparation). They have also been selected, in part, because of the availability of a risk assessment or extensive scientific knowledge and/or the need for such information in conjunction with a CCFH project currently underway.

- *Listeria monocytogenes* in a smoked fish
- *Salmonella* and *Campylobacter* in raw broilers
- *Staphylococcus aureus* enterotoxin in a crème-filled pastry
- *Vibrio parahaemolyticus* in raw oysters

## **2.4 Utilization of Existing Information**

Wherever feasible, the expert consultation should identify and make use of exiting risk evaluations and risk assessments, particularly in relation to the development of examples pertinent to the current activities of CCFH. In developing methods and practical examples, the consultation should be aware of and take into consideration frameworks and technical information developed by the World Health Organization, the Food and Agriculture Organization and the Codex Alimentarius (e.g., *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CX/FH 05/37/6, 2005), *WHO Expert Consultation - The Interaction between Assessors and Managers of Microbial Hazards in Food*, (Kiel, Germany, March 2000), and *WHO Expert Consultation - The Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts*, (Kiel, Germany, March 2002), “Microorganisms in Foods 7: Microbiological Testing in Food Safety Risk Management,” (ICMSF, 2002).

## **2.5 Time Frame**

Since the results of the consultation are needed to provide concepts, techniques, and examples needed as reference material for the completion of several active documents being developed by CCFH, the final report of the consultation is needed in 14 months.

# FAO/WHO Concept Note for future work on the Development of Practical Risk Management Strategies based on Microbiological Risk Assessment Outputs

**Working title:** FAO/WHO Consultation on the Development of Practical Risk Management Strategies based on Microbiological Risk Assessment Outputs

**Background:** In 1999, following the request of the Codex Alimentarius Commission, FAO and WHO began work in the area of microbiological risk assessment (MRA). This new area of work sought to facilitate the development of, and to support new risk management strategies to address the problem of microbiological food safety. Although the previous decade saw great advancement in this area with the application of Good Hygienic Practices (GHPs) and the Hazard Analysis Critical Control Point (HACCP) system these are not always sufficiently effective and new approaches are needed to enhance these systems or support the implementation of other/additional microbiological risk management strategies. For example, the application of HACCP is limited or non-existent in the primary production of food, although the abundance of microbial agents in this environment sometimes seriously endangers product safety. Risk management also needs to provide solutions in this area and this may be achieved through the identification of effective intervention schemes based on risk assessment.

Risk assessment as a tool can be used to thoroughly examine a food production system, to give a better insight of its strengths and weaknesses in terms of microbial control and provide an estimate of the risk to the consumer, based on the current system or as a result of simulated changes to a system. Therefore, as a tool risk assessment has the potential to allow the user develop targeted and effective risk management strategies.

To date FAO/WHO have developed risk assessments on *Salmonella* in eggs and broiler chickens, *Listeria monocytogenes* in ready-to-eat foods, *Vibrio* spp. in seafood and *Campylobacter* spp. in poultry. These were undertaken in response to specific requests from the Codex Committee on Food Hygiene (CCFH). Despite the fact that the risk assessments have addressed specific questions posed by Codex, the international risk management task to convert the output of these risk assessments into effective risk management strategies has proved to be difficult. There are a number of possible reasons for this. MRA is a new tool and has only recently been used at the national level and so this very limited experience of its use in countries has hindered the comprehension of how it could be used at the international or Codex level.

Also, the outputs of MRA are different to those of chemical assessments, which have been underway for many years. The “bright-line” numerical outputs of chemical assessments, often related to a definable minimum dose below which no symptoms appear, are used directly to develop standards. With MRA, dealing with a living agent which can react differently in different conditions, leads to a more complex assessment. MRA can provide a lot of valuable and insightful information but not the “bright-line” numerical outputs many risk managers are familiar with. Compounding this complexity is the fact that for infectious microorganisms no minimum infectious dose applies, even one single organism can cause disease. Some other complicating factors include data gaps relating microbial epidemiology and ecology, and the complexities of the dose-response relationships, influenced by many human and environmental conditions. All these factors have contributed to a basic conceptual problem as to how MRA can be used.

In 2002 FAO /WHO convened a meeting in Kiel<sup>16</sup> to develop guidelines for the Application of Microbiological Risk Assessment in the elaboration of standards, guidelines and related texts. While this meeting provided some very useful outcomes and advice in the area of getting a risk assessment carried out, primarily because there was some good experience in that area at the national level and a number of lessons had been learned, the outcome in terms of guidance on using the outputs of the risk assessment in risk management was less concrete. Also the present Codex draft Principles and Guidelines for Microbiological Risk Management<sup>17</sup> despite its significant merits and progress in development, may suffer from similar deficiencies in terms of providing specific practical guidance.

The struggle at both the national and international levels to effectively and efficiently use microbiological risk assessment as a tool to support risk management has highlighted the need to revisit this area in more detail and look at the experiences in the countries that are using MRA with the objective of developing practical guidance that would facilitate the work of national and international risk managers.

**Purpose and scope:** This consultation aims to delineate the different ways in which MRA can contribute to the enhancement of current, or the development of new and effective risk management strategies for implementation at different steps along the food chain. The final output of the meeting will be a guidance document for the preparation of risk management measures using MRA and associated scientific information that would serve both national and international microbiological risk management.

In doing the above a number of issues, as mentioned below, will have to be considered.

- What difficulties or stumbling blocks have been encountered so far in developing practical Risk Management (RM) Guidance based on the outputs of MRA and associated or relevant scientific information? What is missing? What can be done to overcome these?
- What kind of risk management actions can be developed using MRA in combination with other scientific and technological information
- How can MRA be used together with other RM support tools to develop better risk management strategies at practical level such as Codes of Hygienic Practice and HACCP systems with interventions for risk reduction at primary production and processing level?
- MRAs are developed both nationally and internationally. While national or one country risk assessments are usually for use only in that country, international risk assessments preferably should be set up to be used both at the international level by Codex and at country level, although not necessarily in the same way. Therefore the consultation will also examine how a risk assessment can be used under different circumstances as the basis for risk management actions. (See Figure below)
- Due to regional, cultural and geographical differences across the world, risk management guidance produced, particularly at the international level will have limitations in terms of its specificity and is usually more generic in nature. Therefore, the risk management guidance will need to be adapted to country or regional situations. The level of adaptation required will vary depending on the specificity of the guidance document. How can MRA and other scientific information be used to make such management guidance as useful as possible and facilitate its adaptation at the national level?.

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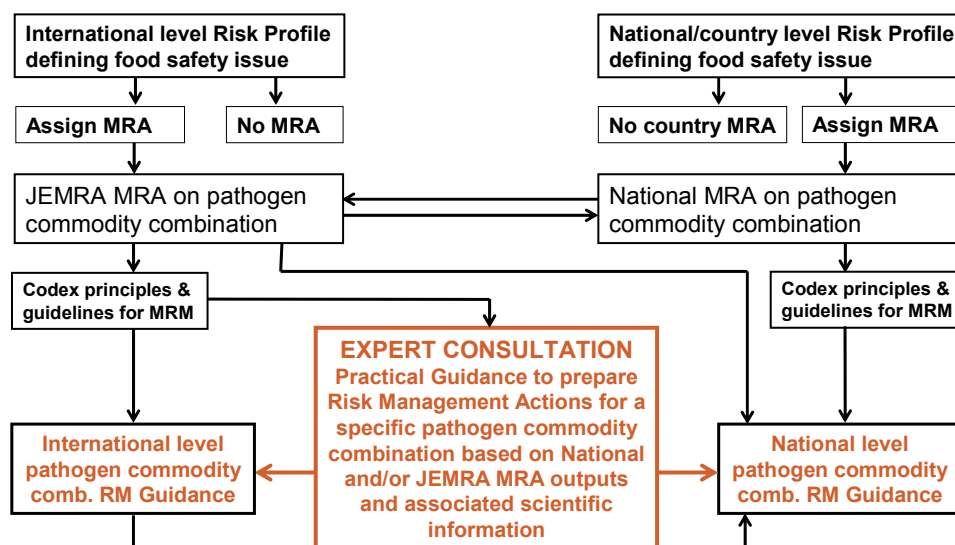
<sup>16</sup> FAO/WHO, 2002. Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. Report of a Joint FAO/WHO Consultation, 18 – 22 March 2002, Kiel, Germany.

<sup>17</sup> Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM), Codex Committee on food Hygiene, 37<sup>th</sup> Session Buenos Aires, Argentina, 14- 19 March 2005 (CX/FH 05/37/6)

- MRAs may be qualitative or quantitative in nature so it will be necessary to consider how the type of MRA will impact the way it is used in risk management. The same question applies to the use of information from Risk Profiles as a basis for microbiological risk management.
- Technical and economic feasibility and data availability are also issues that have to be considered in the risk management process. While this is recognized the current consultation will not address these in detail but focus on the optimal use of MRA outputs and associated scientific information in developing risk management strategies.

**Workplan:** The tentative date for implementation of this meeting would be June (20 – 24) or July (11 – 15) 2005. This would allow 5- 6 months for “call for experts” and selection of experts, preparation of background documents and meeting logistics. FAO/WHO will need to define the criteria for the selection of the experts and identify or define the case studies (Country experiences) that will be analysed during the meeting. Consideration will be given to the establishment of a core group of experts to assist FAO and WHO identify and prepare the background papers. The work of the consultation might also be facilitated through the implementation of an electronic discussion group in advance which could involve all invited experts and prepare the groundwork for the meeting in Kiel.

### ***Practical Guidance for Risk Management at national and international level, based on interactive application of MRA***



## Members of the pre-meeting working groups

<b>Paper no.</b>	<b>Title</b>	<b>Members of the working group</b>
<u>1</u>	<u>Framework document:</u>	Martin Cole, USA Steve Hathaway, New Zealand Jean Louis Jouve, France (coordinator) Riita Liisa Maijala, Finland Alan Reilly, Ireland
<u>2</u>	<u>Case study: <i>Staphylococcus aureus</i> in cheese</u>	Claus Heggum, Denmark Servé Notermans, Netherlands (coordinator) Moez Sanaa, France Rima Haidar Zu'mont, Jordan
<u>3</u>	<u>Case study: <i>Escherichia coli</i> O157:H7 in raw meat</u>	Geraldine Duffy, Ireland Dan Engeljohn, USA Anna Lammerding, Canada (coordinator) Bruce Tomkin, USA
<u>4</u>	<u>Case study: <i>Listeria monocytogenes</i> in smoked fish</u>	Robert Buchanan, USA (coordinator) Tom Ross, Australia Richard Whiting, USA
<u>5</u>	<u>Case study: <i>Vibrio vulnificus</i> in shellfish</u>	Angelo DePaola, USA Ron Lee, United Kingdom Deon Mahoney, Australia Irma Rivera, Brazil Mark Tamplin USA (coordinator)
<u>6</u>	<u>Case study: <i>Salmonella</i> Enteritidis in eggs</u>	Paul Cook, United Kingdom Tine Hald, Denmark (coordinator) Fumiko Kasuga, Japan Hajime Toyofuku, Japan
<u>7</u>	<u>Case study: <i>Campylobacter jejuni</i> in poultry</u>	Ivone Delazari, Brazil Aamir Fazil, Canada Emma Hartnett, Canada Arie Havelaar, the Netherlands (coordinator) Ron Lake, New Zealand Birgit Nørrung, Denmark

## Key findings of the pathogen-commodity case studies

The case studies presented in this Annex were prepared to be used as background papers for the FAO/WHO expert meeting on "The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies". Some of the key conclusions, recommendations and "lessons learned" from this work are presented here on a case by case basis.

*The case studies outlined in this Annex were prepared by groups of independent experts to be used as background papers for the FAO/WHO expert meeting on "The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies" (Kiel, Germany, April 2006). The views expressed therein are those of the authors and do not necessarily reflect the views of the Food and Agriculture Organization of the United Nations or the World Health Organization. This material is provided to facilitate transparency and international discussion on, and further development of this issue. It should not in any situation be referenced as the opinion of FAO, WHO or the Codex Alimentarius.*

The full text of the case studies will be made available on the FAO and WHO webpages<sup>1</sup>. This overview focuses on some of the key findings and lessons learned in each of the case studies as well as providing a flow sheet of the process considered in each study.

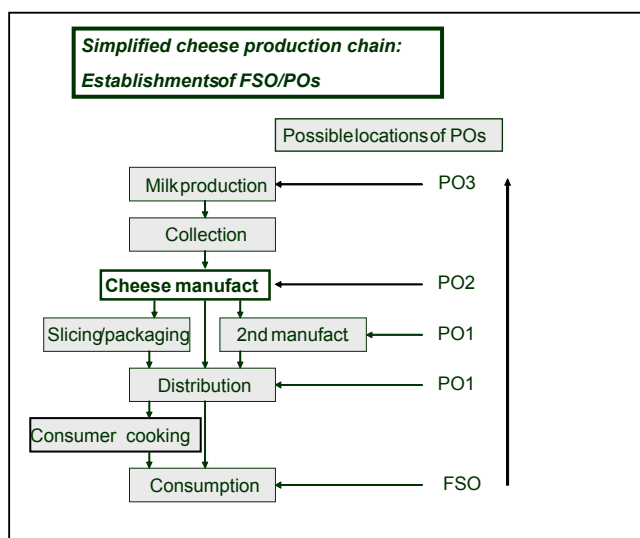
### Case study *Staphylococcus aureus* in cheese

#### Current uncertainties:

- Presently no risk assessments available on *S. aureus* in any food
- There is limited information about toxin production of most sero/geno types of *S. aureus*
- No dose-response relationship available. Only some 'epidemiological' data for SEA (minimal dose)
- There are many different types of cheeses
- Portions and portion size consumed are not well established
- Uncertainty about reported cheese associated *S. aureus* diseases

#### Establishments of FSO/POs and PCs

- FSO : the hazard is the *Staphylococcus* enterotoxin ( $\leq 1.0 \mu\text{g}$  per consumed portion)
- PO : *S. aureus* in the cheese chain ( $\leq 10^5$  cfu of *S. aureus*/ml or g in the chain)



<sup>1</sup> FAO website: [http://www.fao.org/ag/agn/jemra/riskmanagement\\_en.stm](http://www.fao.org/ag/agn/jemra/riskmanagement_en.stm)  
WHO website: <http://www.who.int/foodsafety/micro/jemra/en/index.html>

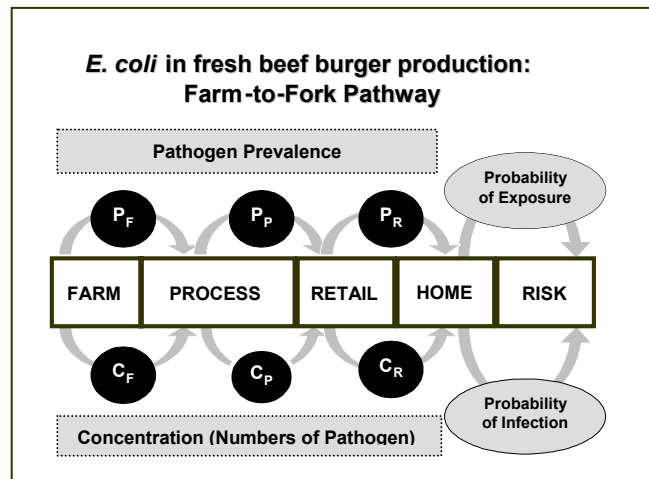
### Lessons Learned

- In the absence of a dose-response relationship it is not possible to link control measures to an explicit level of protection. Nevertheless epidemiological information on the toxicology of enterotoxin enables the application of simple and well established control measures that are effective.
- The current approach to control enterotoxin production in cheese can easily be transformed into a risk-based approach and simple and conservative (given the data gaps indicated above) mathematical modelling can be used to support the hazard analysis approach.

### **Case Study: *Escherichia coli* O157:H7 in Fresh Raw Ground Beef**

#### Potential Points of Intervention & Control Strategies

- On-farm: Contamination routes and population dynamics are unclear. Current strategies to prevent, reduce or eliminate colonization of animals are not 100% effective. Possible interventions: GAP, QA Programs, HACCP Principles
- Transport & holding: leads to increased faecal shedding. Possible intervention: Limit stress on animals
- Abattoir: Poor slaughter practices lead to carcass contamination; improper chilling allows proliferation. Possible interventions: apply HACCP systems and GHP, decontaminate hides, carcasses



#### Application of MRA results to develop risk-based management strategies

- Establish an FSO to achieve 'desirable' level of health protection particularly difficult or simply not appropriate for raw foods handled in the home (variability & uncertainty post-processing)
- Establish a target: This could be the establishment of a Performance Objective for trimmings and/or raw formed ground beef patties
- Range of prevalence and concentrations of *E. coli* O157:H7 considered within the risk model
- Outcome: By defining PO for raw beef trim or raw ground beef, consequential dose at time of consumption, frequency of consumption (FSO values) and associated probability of illness (level of protection values) are estimated
- Context of level of protection/FSO discussions – feasibility of achieving necessary PO can help inform this.

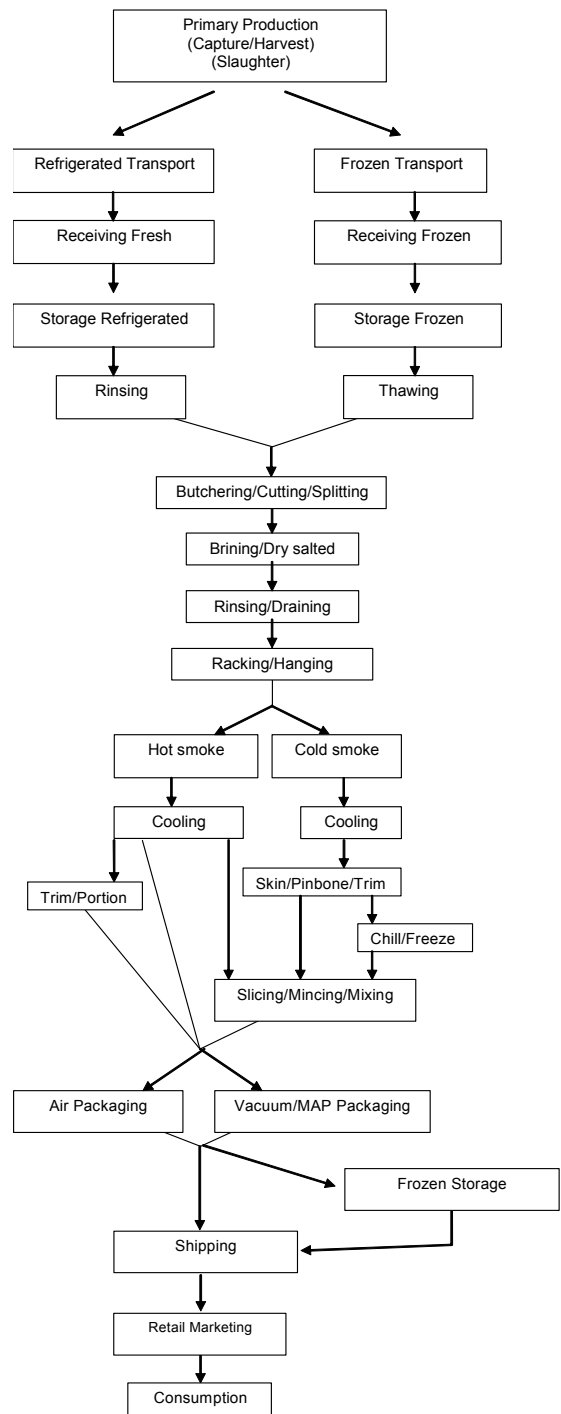
### Lessons Learned

- MRAs must be 'designed' to be capable of being 'queried' ("what-if" questions)
- Relied on risk assessment team members to generate exposure (dose) and risk estimates based on "what-if" prevalence/concentration limits set for raw trim/ground beef
- New research may have significant impact on findings of completed MRAs
- Selecting measures in terms of effectiveness (& cost-benefits) important to using MRA outcomes for selecting risk-based management options
- Depending on purpose & scope of MRA:
  - Managers & assessors interaction prior to and during MRA important
  - Iterative process to identify and assess points of interventions
  - Useful MRA outputs for similar 'matrices': comparisons ('scenario analyses') with alternative criteria at alternative junctions
  - Involvement of economists at the beginning, middle and end of conducting MRA - iterative process also

## Case Study: *Listeria monocytogenes* in Smoked Fish

### Lessons Learned

- There is a great deal of variability in the processing of hot-smoked and cold-smoked salmon. Without simplifying assumptions of how the key steps are handled by a majority of the industry, one could easily get lost in the details. This could be avoided by using the more sophisticated probabilistic approach, but this is more difficult to explain.
- The measurement of variability and uncertainty will have to be dealt with ultimately. For the purpose of this case study it was simplified by performing a deterministic assessment. Variability and uncertainty have to be considered in more detail to get better estimates of the risk reductions achieved
- The techniques for relating MCs to POs are still in its infancy and consensus on approaches has not been reached. FAO/WHO should encourage and support the development of “user-friendly” models to enable a broader range of risk managers to perform these calculations.
- Making consistently conservative assumptions in a multiple step food processing series, has the potential for producing POs and FSOs that are unrealistically stringent; Providing a series of potential POs, FSOs, and ALOPs was found to be useful, providing the risk managers with a series of options and avoiding having the risk assessors make the risk management decision.
- There are often multiple combinations of control measures that can achieve an FSO. For example, if cold-smoked salmon was shipped frozen to retail markets, then growth would be reduced by approximately 1 Log(CFU/g). Conversely, an intervention step at final packaging that reduced *L. monocytogenes* by 1 Log(CFU/g) would give an equivalent degree of risk reduction. This approach is consistent with establishing stringency without hampering innovation by stipulating mitigation approaches or locations along the food chain



## Case Study: *Vibrio vulnificus* in Oysters

### Control options

- Oyster Harvest: Temperature, Salinity
- Post-harvest handling: Time to place on ice
- Post-harvest processing: Inactivation techniques
- Consumption

### Post-harvest processing

- *V. vulnificus* is sensitive to most inactivation techniques
- Several PHP methods exist for reducing *V. vulnificus* load in oysters (Heating (pasteurization) at 50°C, Freezing with extended frozen storage, High hydrostatic pressure)

### Approaches

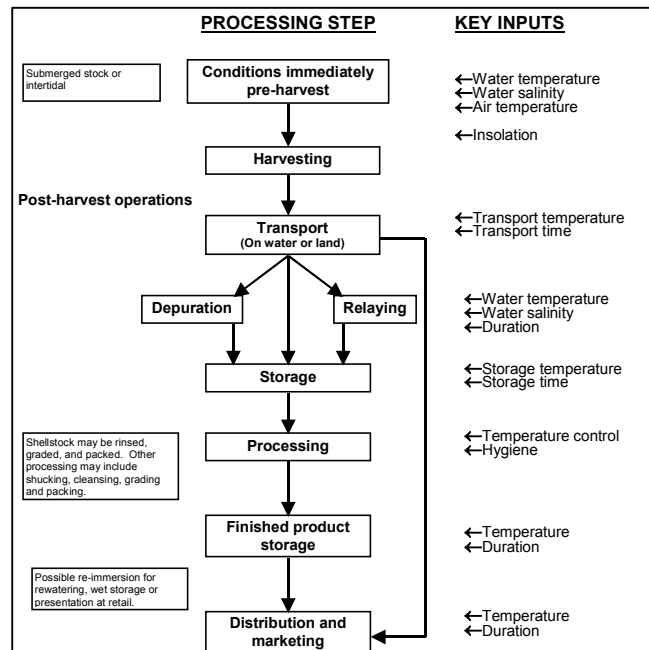
- Examined the impact of selected interventions on the level of foodborne illness
- Considered these interventions in the context of an ALOP – considered a range of targets and identified the interventions that would achieve these targets

### Uncertainties

- Impact of different environmental conditions on *V. vulnificus*
- Survival behaviour of *V. vulnificus* in different species of oyster
- Dose-response models
- Stain virulence

### Lessons Learned

- Comparatively simple task because of availability of detailed Gulf Coast data, single vehicle, limited cross-contamination, raw consumption, etc
- Can be applied to other locations including developing countries – requires access to data *e.g.* production and environmental data, % raw consumption, at-risk populations, etc
- Need to understand the impact of interventions including data on the costs.
- The risk assessment model for *V. vulnificus* in oysters represents a good starting point for countries wishing to undertake a similar risk assessment on domestic oysters and to develop risk management approaches based on appropriate levels of protection
- Adaptability of the model to other countries and regions is contingent on access to extensive and reliable local data



## Case study: *Salmonella* Enteritidis in table eggs

### Identification of options for intervention at the different level of the production chain

Options in primary production:

- Prevent introduction of *Salmonella*
- Control colonisation of the hens (reduce transmission)
- Reduce the number of infected eggs

Whenever possible the effectiveness of the different intervention methods for reducing flock prevalence and/or human incidence was quantified

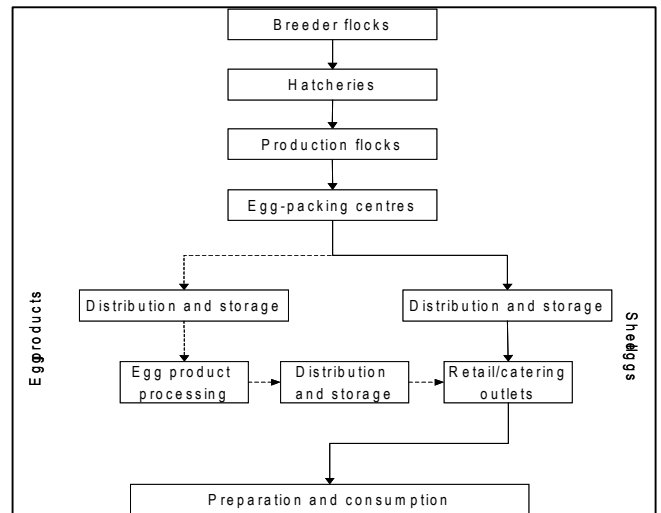
### Case study – Aim of strategy

- All shell eggs from commercial layer flocks should be free of *Salmonella*
- Top-down eradication
- Diverting eggs from known infected flocks

Different measurable objectives with an attached timeframe need to be determined:

- ALOP – proportional reduction of the human incidence (cases per 100,000) of S.E.
- PO – Proportion of infected layer flocks

Figure x. Flow diagram of the production of table eggs. Dashed lines indicate that the risk management strategies for egg product were not considered.



### Selection of intervention methods - further down the chain

- Decontamination of packing lines
- Distribute table eggs in a cold chain not exceeding 7°C
- No shelf-life determination proposed, labelling of eggs with date (of lay or shelf life) and origin
- A number of specific recommendations for consumers

### Appropriate Level Of Protection

- Strategy 1: Removing infected parent and pullet flocks
- Strategy 2: Removing infected parent and pullet flocks, and diverting eggs from infected table-egg layer flocks to pasteurisation
- Strategy 3: strategy 2 plus increased biosecurity and distribution in a cooling chain

### Problems encountered

- For pathogens with multiple sources/reservoirs, the question of food attribution arises: How many cases can be attributed to the source in question and how can this be measured/estimated when evaluating
- In this particular case study, we did not find it relevant (or appropriate) to define a FSO.

### Conclusions

- QRA models are valuable for describing the complex dynamics of pathogens during food processing and evaluating the relative public health effect of different interventions strategies – alone and in combination
- They are less useful for predicting accurate public health outcomes e.g. risk estimates; Burden of illness estimates will probably in many circumstances be more accurately assessed using “traditional” epidemiological methods

## Case study: *Campylobacter jejuni* in broiler meat

### Application of QMRA models to the following interventions

- Reducing prevalence at the farm
- Logistic slaughter
- Scheduling highly contaminated flocks
- Decontamination
- Domestic kitchen

### Logistic slaughtering

- Prevent cross-contamination from infected to non-infected flocks by separate or time-ordered processing
- Cross-contamination is expected to lead to increased between-flock prevalence but to low-level contamination of carcasses only
- Logistic slaughtering may not be an effective, risk models can be used to set microbiological criteria

### Intervention strategy

- Find the best place in the food chain for a Performance objective (PO)
- Find the best microbiological test; filter out the largest probabilities of illness, but don't waste low risk meat
- Scheduling reduces peak exposures, risks are mainly associated with high exposure
- Decontamination increases efficiency of scheduling

### Decontamination

- Reducing numbers may be more efficient than reducing prevalence
- A reduction in numbers of 100-fold is expected to have a strong impact on risk
- Freezing reduces *Campylobacter* numbers

### Domestic kitchen

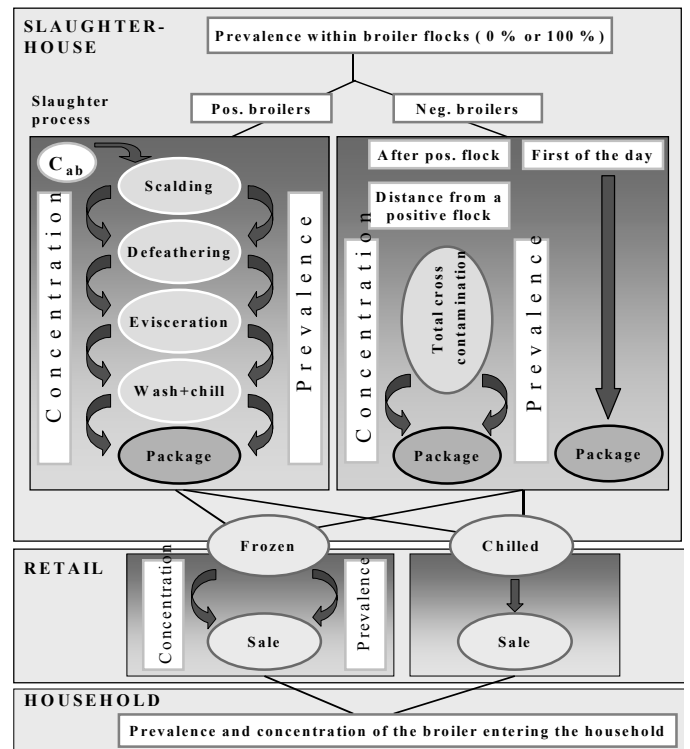
- Main risk from *Campylobacter* on broiler meat is associated with cross-contamination, undercooking poses a smaller risk: preparation hygiene is a key risk management strategy
- Setting an FSO is not considered appropriate, for the food carrying bacteria is undefined

### Lessons learned

- For *Campylobacter* on broiler meat, the FSO exists in theory but cannot be expressed in any meaningful form; articulation of an FSO or a PO is not considered a necessary step
- A risk assessment model can be used to directly bridge any parameter in the food chain and the consumer risk
- Interventions at different points in the food chain can result in risk reduction

### Conclusions and recommendations

- FSOs are not an appropriate risk management option for *Campylobacter jejuni* in broiler meat, because cross-contamination is assumed to be the major route of contamination.
- Backward calculation from an ALOP to a PO, PC or MC is technically very difficult if variability and/or uncertainty are taken into account. Forward calculation is technically possible and the preferred option.
- There is a need for a more precise definitions of the new food safety concepts and more guidance on their practical implementation.



### List of meeting participants

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**Karen L. Hulebak**, US Department of Agriculture, United States of America  
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APPENDIX III from the report of the 37th session of the Codex  
Committee on Food Hygiene (ALINORM 05/28/13)

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

**(at Step 5 of the Procedure)**

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

### INTRODUCTION

Diseases caused by foodborne microbial hazards<sup>2</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>3</sup> and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment<sup>4</sup>. 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).

### 1. SCOPE

These principles and guidelines provide a framework for the MRM process and are intended for use by Codex and countries<sup>5</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>6</sup> and consumers who are involved in MRM on a day-to-day basis.

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<sup>2</sup> Foodborne hazards include (but are not limited to) pathogenic bacteria, viruses, algae, protozoa, fungi, parasites, prions, toxins and other harmful metabolites of microbial origin.

<sup>3</sup> Adopted by the 26<sup>th</sup> session of the Commission (see ALINORM 03/41). Note that the development of working Principles for Risk Analysis to be applied by Governments is under consideration by the CCGP (see ALINORM 04/27/33A).

<sup>4</sup> See CAC/GL-30 (1999).

<sup>5</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 Procedural Manual – 14<sup>th</sup> Edition – p. 6.

<sup>6</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).

## 2. DEFINITIONS

The definitions of risk analysis terms related to food safety incorporated in the Procedural Manual of the CAC<sup>7</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>8</sup>, 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*<sup>9</sup>, and the definition of **interested parties** included in *The Working Principles for Risk Analysis for Application in the Framework of the Codex*<sup>10</sup> shall apply too.

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 under development in the draft *Guidelines for the validation of food hygiene control measures*<sup>11</sup>.

**Risk manager**<sup>12</sup> is defined as follows: a national or international governmental organisation with responsibility for MRM.

For the purpose of this document, the FSO, PO and PC shall apply to microbial hazards.

## 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<sup>13</sup> differences in hazards in the food chain and regional differences in available risk management options.
- PRINCIPLE 8: MRM decisions should be subject to review and revision.

## 4. GENERAL CONSIDERATIONS

Codex and government decisions and recommendations have as their primary objective the protection of the health of consumers. 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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<sup>7</sup> Procedural Manual, 14<sup>th</sup> Edition (pp.43-47, English version)

<sup>8</sup> Annex to CAC/RCP 1-1969, Rev. 4-2003

<sup>9</sup> See CAC/GL 21 - 1997

<sup>10</sup> See ALINORM 03/41

<sup>11</sup> Document CX/FH 04/9

<sup>12</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>13</sup> See CX/FH 98/13 on the meaning of the word "regional"

MRM should follow a structured approach that includes preliminary MRM activities, identification and selection of MRM options, implementation of MRM options, 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>14</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 and 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 use patterns associated with food, consumers' perception and the prevalence of specific adverse health.

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.

**Annex I** illustrates the typical components of the MRM process.

## **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 decision/emergency measure] be taken by the risk manager without further scientific consideration (e.g. withdrawal / recall of contaminated products). Countries will often not be able to delay taking an [emergency] action when there is an immediate public health concern demanding an urgent response.

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<sup>14</sup> See Procedural Manual, 14<sup>th</sup> Edition : Criteria for the Consideration of the others factors (p.188)

[Where scientific knowledge is insufficient, it may be appropriate to apply a precautionary approach through provisional decisions<sup>15</sup>. 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. **Annex II** 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 [provisional] decision (see section 5.1 above). In some cases, no further action may be needed.

Within CCFH, the compilation of a risk profile may result in the establishment of a working group to evaluate the food safety issue in the international context, considering the results of any FAO/WHO Joint expert consultation on MRA (JEMRA) or national MRA concluded or ongoing. The risk profile provides the Committee with an initial analysis and recommendations related to 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>16</sup>. National governments should establish a MRA policy relevant to their circumstances, in advance of the microbiological risk assessment.

## 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 can be reviewed by the scientific community parties.

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 adequate to proceed further in developing and/or evaluating and deciding on suitable MRM options, [or deciding on provisional MRM options] if some elements of the MRA need further study.

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<sup>15</sup> See the Draft working principles for risk analysis to be applied by countries, under consideration by the CCGP (see ALINORM 04/27/33A)

<sup>16</sup> See Section on Risk Assessment Policy – p. 102-103 (Procedural Manual – 14th Edition – English version). This reference should be extended as soon as the Codex Alimentarius Commission adopts the Proposed Draft Working Principles for Risk Analysis for Food Safety, currently under elaboration.

## 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 acceptable level and any practical issues regarding the implementation of the selected MRM options that need to be managed.

Examples of 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;
- furnishing of data that demonstrate relationships between different risk estimates and FSOs,
- compilation of an appropriate guidance document, including specific recommendations and practices. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the 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.<sup>17</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, [traceability/product tracing];
- adapt Codex recommendations and guidance documents 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 POS, PCs and MCs at specific stages of the food/feed<sup>18</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;
- require import certificates for certain products;
- promulgate awareness and develop educational and training programs to enforce or stipulate that:
  - prevention of contamination and/or introduction of hazards is addressed at all relevant stages in the food/feed chain;
  - rapid withdrawal/recall of food procedures are in place, including appropriate [traceability/product tracing] for effectiveness;

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<sup>17</sup> Statement adopted by the 24<sup>th</sup> Session of the Commission (ALINORM 01/41 para. 81)

<sup>18</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.

- properly labelling with 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 practical should generally involve 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 various 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 (see below).

### 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 as far as possible some flexibility in options that the industry can use to achieve the desired level of control.

### 6.2.2 Risk-based MRM options

The increasing adoption of risk analysis is allowing more quantitative and 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 development of new MRM tools such as FSO, PO and PC and the enhancement of the scientific basis of existing MRM tools such as microbiological criteria (MC).

It is difficult to relate control measures directly to an ALOP, particularly when it is implicit or expressed in qualitative terms (such as “reasonable certainty of no harm”<sup>19</sup>), and not in quantitative terms (such as a “number of illnesses/year”). Therefore the concept of FSO has been introduced. Effective MRM typically requires that additional risk-based milestones be established at particular steps in the food chain to ensure the ultimate food safety outcome. As a means of addressing this need, PO and PC have been introduced.

There is a hierarchy between the concepts of FSO, PO and PC. Conceptually, an FSO is derived from the ALOP, whereas a PO and/or a PC are derived from an FSO. However, also in the absence of an ALOP or an FSO, the concepts of PO and PC may be potential options for risk managers to guide the establishment of process requirements in operational practice. The availability of a MRA can help in deciding upon the need and for choosing the best step where to apply PO, PC or particular control measures.

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<sup>19</sup> See OECD document

#### 6.2.2.1 Food Safety Objective (FSO)

A food safety objective is defined as “*the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)*”. 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 MRAs. FSOs are seldom verifiable as regulatory standards as they apply at the time of consumption. They 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 observation of the public health status, mainly with the help of epidemiological surveys (see section 8). The other is based on experimental or other scientific evidence 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 the safety of certain products;
- 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).

Notably, FSOs may not be universally common and may take into account regional differences.

#### 6.2.2.2 Performance Objective (PO)

A performance objective is defined as “*the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable*”.

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:

- 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 mediate 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. An MRA can assist in determining such relationships.

An 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 their food safety control system such that the PO (set by government or the individual food business) and the FSO (set by government) are met, the individual food business will have to make provisions respecting their 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. The 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, ...) and the intended use of the end products (domestic consumer handling, ...). Although POs are generally not intended to be verified by analytical means, compliance with POs may need to be verified by other means, such as:

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

#### 6.2.2.3 Performance Criterion (PC)

A performance criterion is defined as “*the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO*”.

PCs are generally set by individual food business. However, PCs 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.

The PC can be expressed e.g., in terms of a desired reduction (or acceptable increase) in the concentration and/or frequency of a hazard in the course of a particular control measure, e.g. the result of a particular treatment.

Generally, PC either relate to a control measure with a microbiocidal and/or microbiostatic effect. A PC for a microbiocidal control measure (e.g. heat treatment) expresses the desired reduction of the microbial population that occurs during the application of the control measure. A PC for a microbiostatic control measure (e.g. chilling) expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied.

Such PCs are often translated by industry or sometimes by competent authorities, into **process criteria**<sup>20</sup> or **product criteria**. For example, if a PC indicated that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criterion would stipulate e.g. 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 reduces 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.

#### 6.2.2.4 Microbiological Criterion (MC)

Consequent to the introduction of the concepts of FSO/PO/PC, the role of MC may expand. There will still be a use for MC in assessing compliance of tested lots or consignments of food/feed when there is no information available on how or under what conditions the food/feed was produced. Obviously, MC may also find utility to verify the continuing effectiveness of all or part of a food safety control system (e.g. HACCP). As such, MC may provide an objective means of verifying that a PO or PC (or a FSO) is met.

For the purpose of food safety control system validation, monitoring or verification, the extent of analytical testing (and consequently the elements constituting the MC) depends on the risk and consequence of loss of control, the degree of uncertainty associated with the control of the hazard, the degree of confidence required, and the statistical methods being employed.

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<sup>20</sup> For the purposes of this document a process criterion is understood to mean “parameters of a control measure that if properly applied have been established as meeting, either alone or in combination with other control measures, a performance criterion” and a product criterion is understood to mean “a physical or chemical attribute of a product that if properly applied as a control measure has been established as meeting, either alone or in combination with other control measures, a performance criterion.”

In general, an MC will have to be more stringent than the PO or PC upon which it is based, in order to assure that the PO is being met with a specified level of confidence. Care must be taken to ensure that the basic assumptions underlying the selection of the parameter to be measured are scientifically valid (e.g., the assumption that the presence and extent of contamination of a food with *Escherichia coli* is directly related to the extent of faecal contamination).

## **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 appropriate targets (POs) that will achieve or contribute to established FSOs;
- 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]<sup>21</sup> 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 information, etc..., and otherwise assist 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, hygienic handling labels, date labels, and public interest messages. Consumer organisations can play a significant role in getting this information to consumers.

### **8. MONITORING AND REVIEW OF MRM OPTIONS**

#### **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. Ongoing monitoring is essential to establish a baseline for comparing the effectiveness of new MRM options. 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 are needed 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 options. 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;
- environmental hygienic data on 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:

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<sup>21</sup> See on-going work of the CCFICS

- 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 options**

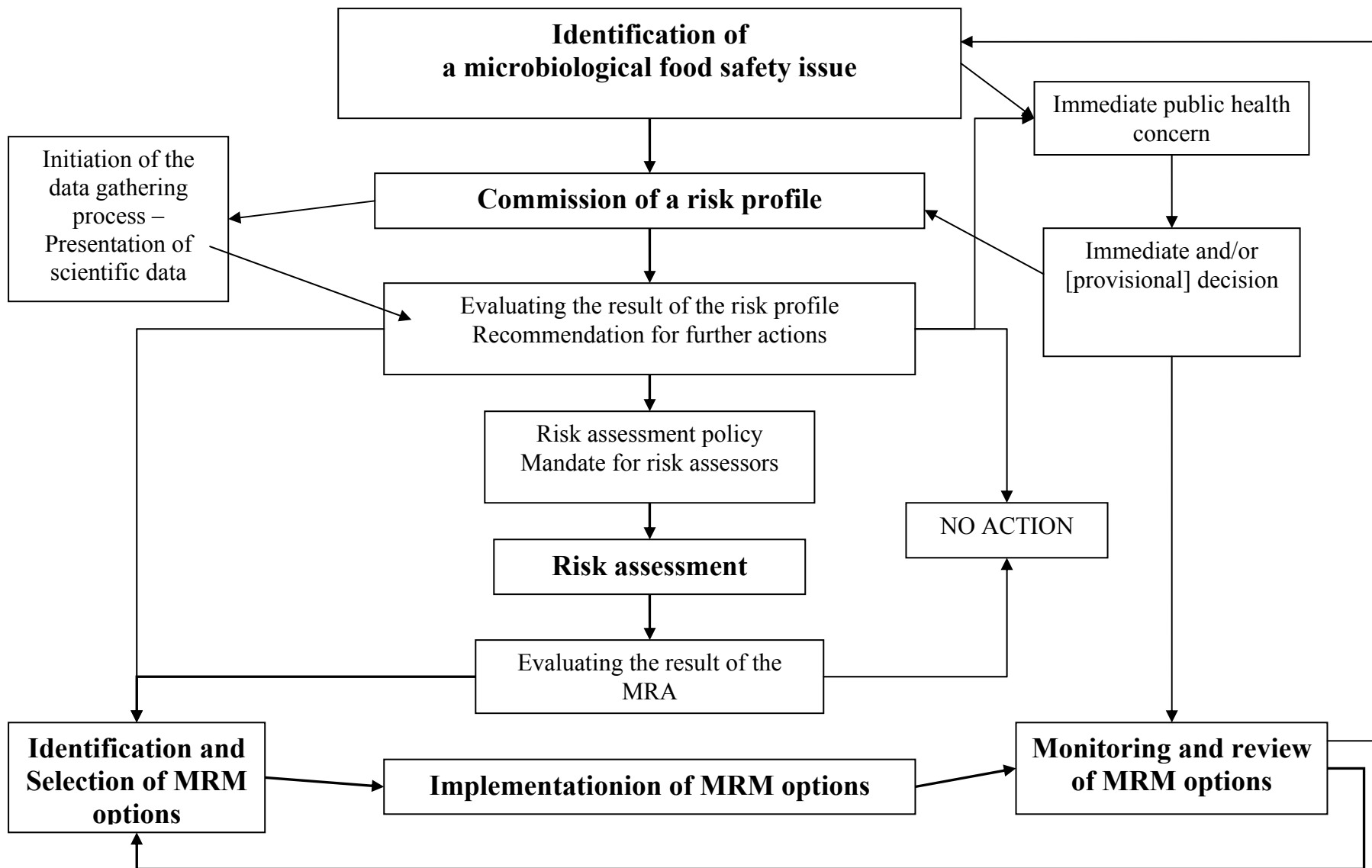
The effectiveness and appropriateness of the MRM options selected, and of the implementation thereof, need to be reviewed. Review is an integral part of the MRM process and ideally should take place at a predetermined moment in time or whenever relevant information becomes available. Criteria for review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

Planning periodic review of MRM options 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 option implemented or to substitute the option for another one.

MRM options should be reviewed when new options 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 options 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 (including Codex) consider to take, should be made public and communicated to all interested parties.



## ANNEX II

### 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 III: (Under development)**