codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT
(AT STEP 3 OF THE PROCEDURE)

Prepared by France with assistance of Argentina, Australia, Belgium, Canada, Denmark, Finland, Germany, Hungary, India, Italy, Netherlands, New Zealand, Norway, Singapore, Sweden, United Kingdom, United States, Consumers International, European Commission, ICMSF, ICGMA and IDF .

Governments and interested international organizations are invited to submit comments or information on the attached Draft Code at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition,* pages 20-21) **to**: Mr. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email uscodex@usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by FAX +39-06-5705-4593 or email codex@fao.org by **25 February 2004.**

BACKGROUND

The Codex Committee on Food Hygiene (CCFH) at its 29th Session (1996) – and the 22nd session of the CAC - agreed that new work should be initiated to develop recommendations for the management of microbiological hazards for foods in international trade.

Since that time, a lot has been done and successive papers have been examined by the Committee each year, lately at the 35th Session in Orlando (January 27th, February 1st, 2003). The Committee discussed the document CX/FH 03/7 providing specific points to be further considered by the group. It was suggested that new work was required in particular (1) to restrict whenever possible the list of terms and definitions and to discuss the concept of FSOs, including its application and the designation of performance criteria at points within or at the end of the food chain, (2) to develop the relationship between risk assessment and risk management, (3) to avoid overlap with the proposed draft Process paper discussed under agenda item 5(a) and to take into account the work done in other Codex committees (e.g., CCGP), (4) to clearly differentiate between specific recommendations applying to Codex and those applying to national governments.

It was agreed that the drafting group led by France, and with the assistance of Argentina, Australia, Belgium, Canada, Denmark, Finland, Germany, Hungary, India, Italy, the Netherlands, New Zealand, Norway, Singapore, Sweden, the United Kingdom, the United States, CI, the European Commission, ICGMA, ICMSF and the IDF, would revise the document at step 3 for circulation, comments and further consideration at the 36th Session of CCFH.

REVISED DOCUMENT

The previous document has been redrafted according to the discussions of the drafting group held in Brussels (3-6 June 2003)[1], and further electronic consultations.

RECOMMENDATION

The Committee is invited to discuss on the attached *Draft Proposed Principles and Guidelines for Microbiological Risk Management* with a view towards its further development.

[1] The following countries and observers were present in Brussels: Belgium, Canada, Denmark, Finland, France, Germany, India, Italy, the Netherlands, New Zealand, Sweden, the United States, the European Commission, Codex Secretariat, ICMSF and the IDF.

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

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INTRODUCTION

Risks from microbiological hazards in foods are of immediate and serious concern to human health.

Effective control of risks arising from microbiological hazards is technically complex. The rise in globalization of the food market increases the challenge to manage these risks. Risk analysis, including its component parts of risk assessment, risk management and risk communication, should be used as a tool in evaluating and controlling microbiological hazards to help ensure the protection of consumers.

Risk managers need to evaluate the risk that the hazard poses to public health, decide what appropriate action, if any, should be taken and implement the programs chosen to control the risk. A four-step process involving (1) preliminary microbiological risk management (MRM) activities, (2) identification and evaluation of MRM options, (3) selection of MRM options and implementation of MRM decisions, and (4) monitoring and review of MRM decisions is envisioned as a systematic means of addressing microbiological food safety concerns.

As a mean of completing the first step in the MRM process, the development of a risk profile is recommended. This decision tool provides an initial assessment of the problem and the options available to address the concern. On the basis of the risk profile, a range of initial decisions may be reached such as identification of interventions that are most promising for controlling the hazard, need to acquire more information, and the commissioning of a microbiological risk assessment (MRA).

Within the MRM process, where feasible it can be beneficial to articulate an appropriate level of protection (ALOP), either qualitatively or (preferably) quantitatively. This facilitates comparison of the current risk with the level of protection desired. An ALOP is most often expressed in a range of terms such as a broad public health goal, the probability of an adverse public health consequence, or an incidence of disease. However, there is a need to derive from the ALOP terms that give practical guidance to food industry (i.e., primary production, food processing, catering, distribution, and retail) on the desired level of control of the hazard in the food. Terms intended to provide this practical guidance are introduced in this document, i.e., Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC).

The following principles and guidelines present the different components of MRM, identifying factors and concepts that should be considered at each step of the process. They should be read in close conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*[2] *and* the *Principles and Guidelines for the Conduct of a Microbiological Risk Assessment*[3]. Countries, organizations and individuals involved with MRM are encouraged to review and utilize the guidelines in concert with technical information developed by the *World Health Organization,* the *Food and Agriculture Organization* 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 Microbiological 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, Draft Report Kiel, Germany, March 2002).*

1. SCOPE

These principles and guidelines provide a framework both on the MRM process itself –intended for Codex and for countries- and on the implementation of MRM decisions -intended for countries. They additionally provide guidance on the application of MRA within the MRM process.

The information in this document should also be useful for industry and other interested parties who are involved in the establishment and application of food safety control measures that meet a desired level of risk control.

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[2] Adopted by the 26th 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 03/33A)

[3] See CAC/GL-30 (1999)

Where specific recommendations presented in the document apply only to Codex, or only to countries, this is so noted in the text. When any recommendation concerning this separation is not specified, the section applies both to Codex and to countries.

2. DEFINITIONS

The definitions of risk analysis terms related to food safety incorporated in the procedural manual of the CAC[4], shall apply. See definitions of **hazard, risk, risk analysis, risk assessment, hazard identification, hazard characterization, dose-response assessment, exposure assessment, risk characterization, risk management, risk communication,** and **risk assessment policy, risk profile, risk estimate**[5], **product tracing/traceability**[6]**, equivalence**[7]**.**

The definitions from T*he Guidelines for the Application of the HACCP System*[8], e.g. **control measure, step** or **critical control point**, and the definition of a **microbiological criteria** included in T*he Principles for the Application of Microbiological Criteria for Food*[9] shall apply too.

The definition of the **ALOP** is the definition in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

For the purpose of this document, the following terms are defined:

Risk manager: A representative of a government at a national level or regional level or a representative of an international organization who has the responsibility for MRM.

Food Safety Objective: The maximum frequency and/or concentration of a [microbial] hazard in a food at the time of consumption that still provides the appropriate level of protection.

Performance Objective: The maximum frequency and/or concentration of a [microbial] hazard in a food at a specified step in the food chain before time of consumption that will ensure the achievement of an FSO or ALOP, as applicable.

Performance Criterion: The desired effect in the frequency and/or concentration of a microbial hazard(s) in a food that must be achieved by the application of one or more control measures to meet or contribute to meeting a PO or a FSO.

3. GENERAL PRINCIPLES

The *working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*[10] shall apply for the conduct of MRM by Codex and countries. The following additional principles shall also apply:

- PRINCIPLE 1: Protection of human health should be the primary consideration in the conduct of MRM.

- PRINCIPLE 2: MRM should take into account the entire food chain, including feed and imported food and feed.

  The microbiological safety of food is typically assured by an integration of controls at primary production, product design, process control, and the application of good hygienic practices during manufacture, labeling, and safe handling during distribution, storage, sale, preparation and use, such that the desired level of risk control is achieved. As such, risk managers should consider MRM options from

[4] Procedural Manual, 12th edition, FAO/WHO (13th edition in preparation)
[5] These 3 last definitions have been included in the Procedural Manual by 26th session of the CAC (ALINORM 03/41).
[6] The CCGP is being to develop a definition for product tracing/traceability within the framework of the Codex (see ALINORM 03/33A). The definition suggested in the document for 35th session of the CCFH was: "a MRM tool that provides the ability to identify by means of paper or electronic records, a food product and its producer, from where and when it came and to where and when it was sent".
[7] 26th session of the CAC
[8] Annex to CAC/RCP 1-1969 rev 3 (1997), revised by 26th session of the CAC
[9] See CAC/GL 21 - 1997
[10] Adopted by the 26th session of the CAC (see ALINORM 03/41)

farm to table, and not restrict their consideration to a single stage in the food chain. MRM should improve appropriate food safety tools and infrastructures (e.g. regulatory enforcement, HACCP, food product tracing/traceability systems).

- PRINCIPLE 3: Industry has the responsibility for producing and marketing safe products.

- PRINCIPLE 4: MRM should follow a structured process, generally described in 4 chronological steps: preliminary MRM activities, identification and evaluation of MRM options, selection of MRM options and implementation of MRM decisions, monitoring and review of MRM decisions.

- PRINCIPLE 5: The basis of MRM decisions should be transparent and include clear, interactive communication with all interested parties[11].

  The communication process should include public information and consultation, as appropriate. The extent and nature of the communication will depend on the urgency, the complexity and uncertainties of the matter and the impact of subsequent food safety measures.

- [PRINCIPLE 6: A functional separation between MRA and MRM should be maintained, while simultaneously assuring that the interactions essential to development of a meaningful MRA are realized.

  For Codex, MRM is carried out by the CCFH, while MRA is conducted by the FAO/WHO joint expert group on MRA (JEMRA). In countries, competent authorities play a pivotal role in MRM and MRA. Risk managers and risk assessors should be different individuals or organizations. However, recognizing that developing countries have limited resources, risk assessors and risk managers may perform dual roles in these countries.]

- [PRINCIPLE 7: Risk managers should establish, and follow a MRM policy.

  MRM policy provides guidance on uniform procedures and practices to be undertaken in the development and implementation of MRM programs, the determination of MRA policy, establishment of MRM priorities, allocation of resources (human, financial, time) for addressing a food safety issue, determination of the factors[12] to be used in the evaluation of MRM options (e.g. technical and economic feasibility, traditional and cultural practices, situation existing in developing countries, uncertainty and interpretation of the risk estimate and precautionary approach[13], cost-benefit analysis, consumers' perceptions, comments from external experts and interested parties, scope and extent of risk communications). The goal of the MRM policy is to assure that the options chosen are scientifically sound, proportionate to the risk identified and not more restrictive of trade than required to achieve an ALOP.]

- PRINCIPLE 8: Risk managers should establish, and follow, a MRA policy to ensure that the MRAs are independent, systematic, unbiased, complete and transparent.

  MRA policy provides a framework for the conduct of MRAs. It requires interaction between risk assessors, risk managers and other interested parties. It may also provide guidance on issues such as calculation and interpretation of uncertainties, allocation of resources, requirements and procedures for peer review and/or interested parties comments. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different MRM options.

- PRINCIPLE 9: The effectiveness of MRM decisions should be periodically reviewed and MRM decisions and programs revised if appropriate.

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[11] Refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organisations" (see *working Principles for Risk Analysis* ALINORM 03/41)
[12] See Procedural Manual, 12 th edition p165: criteria for the consideration of the other factors (…)
[13] See ref. to 24th session of CAC

4. APPROPRIATE LEVEL OF PROTECTION

A key provision of the SPS Agreement is the Appropriate Level of Protection (ALOP), i.e. the level of protection deemed appropriate by the country establishing (a) sanitary measure(s) to protect human health within its territory.

Determining the ALOP is the responsibility of countries. Codex can help the countries by providing information to governments (e. g. with database system) on specific sanitary measures and associated levels of risk thereby facilitating national decisions relating to the ALOP.

For the purpose of these guidelines, an ALOP is a reflection of a particular country's expressed public health goal for (a) food borne microbiological risk(s), relative to the application of specific sanitary measures. The ALOP applies equally to both domestic and imported food. The ALOP should be clearly communicated to the exporting countries.

An ALOP can be implicit or explicit. An implicit one is most often stated in terms of broad public health goals or in relation to legal requirements ("reasonable certainty of no harm"). However, effective implementation of the ALOP may benefit from a more explicit articulation of public health expectations. An explicit description of an ALOP may be in terms of a probability of an adverse public health consequence or an incidence of disease (e.g., the number of cases per 100,000 population per year).

5. PRELIMINARY MICROBIOLOGICAL RISK MANAGEMENT (MRM) ACTIVITIES

The initial phase of managing a microbiological risk involves the identification of a food safety issue, the elaboration of a microbiological risk profile and, if necessary, the commissioning of a MRA.

Annex I illustrates the components of MRM process including the preliminary MRM activities.

In the interests of safeguarding human health and minimizing the incidence of foodborne diseases, the existence of regional differences in the prevalence and level of various pathogens in the food chain should be recognized and taken into account in the MRM process.

Principles which apply in this regard include the following:

- MRM should be based on microbiological prevalence and level data, from the whole food chain and, if appropriate, additionally on disease incidence and prevalence data.
- MRM should take into account the existence of regional differences such as the prevalence and levels of foodborne pathogens in the food chain or such as processing, distributing and eating patterns.
- MRM should take into account prioritisation of risks, e.g. results of risk ranking of hazards carried out at an international, regional or national level.

5.1 IDENTIFICATION OF A MICROBIOLOGICAL FOOD SAFETY ISSUE

A food safety issue is a situation where a real or perceived public health hazard (involving one or multiple pathogen(s) associated with one commodity or many commodities) requires consideration of a MRM activity to manage the associated risk. A food safety issue should be clearly identified and communicated.

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

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 studies, clinical studies, laboratory studies, scientific, technological or medical advances, lack of compliance with standards, recommendations of bodies of experts, public input or perceived barriers to trade.

Some food safety issues identified will require that an immediate [interim] decision be taken without further scientific consideration. Countries will often not be able to delay taking an action when there is immediate pubic health concern. Where scientific knowledge is insufficient, it may be appropriate to apply a precautionary approach through interim MRM decisions[14]. Such actions should be considered temporary. Whenever possible, the time frame or circumstances under which the interim decision will be reconsidered should be articulated when the decision is communicated initially (e.g. reconsideration after the completion of a MRA)

5.2 MICROBIOLOGICAL RISK PROFILE

The risk profile is a decision making tool that presents the current state of knowledge related to a food safety issue, describes various potential MRM options that have been identified to date, and the food safety policy context that will influence further possible actions.

The CCFH *Discussion Paper: Proposed Draft Uniform Procedure for the Elaboration of Microbiological Risk Management and Related Texts* (see CX/FH 04/5 – agenda item 5.a) provides information about appropriate risk profile elements.

Consideration of the information given in the risk profile may result in a range of initial decisions such as commissioning a MRA, gathering more information (possibly with a new risk profile), directly implement MRM decision (see section 5.1 above), or in some cases, no further action needed.

Within Codex alimentarius (CCFH), it may involve the establishment of a working group to evaluate further the risks, consider the results of any JEMRA or national MRAs available or commissioned, and provide the Committee with its initial analysis and recommendations related to possible MRM options. This will typically take the form of a draft MRM guidance document that will be introduced into the Codex step process.

5.3 MICROBIOLOGICAL RISK ASSESSMENT (MRA)

5.3.1 Commissioning of the MRA

The purpose of a MRA is to provide an objective, systematic evaluation of relevant scientific knowledge to help the risk manager make an informed MRM decision.

Agreement on the following points related to the conduct of both quantitative and qualitative MRA are likely to be important to ensure that the MRA meets the needs of the risk manager and is accepted by the scientific community and other interested parties:

- The limitation of the MRA to a specific product-pathogen pair, or if appropriate, a wider assessment,
- The criteria related to data quality that will be used to accept, reject, or appropriately weight data,
- What are the relevant assumptions that should be employed in developing the MRA and how should the impact of these assumptions be described in the MRA,
- The means for presenting the risk characterizations (e.g. cases per serving, cases per year) including how the extent and sources of variability and uncertainties will be presented,

[14] Note that the development of *working principles for risk analysis to be applied by governments* is under consideration by the CCGP (see ALINORM 03/33A)

- The review of the MRA expected by the risk managers including consideration of public requests for information, peer review by expert panels, and acquisition of comments from the public or interested parties.

5.3.2 Consideration of the process and the results of the MRA

The outputs of the MRA should be presented by risk assessors in a manner that can be properly utilized by risk managers in the evaluation of different MRM options. Generally, the presentation is conveyed in two different formats: a technical report, and an interpretative summary for a broader audience.

For the best use of the MRA, risk managers should be fully informed of its strengths and limitations, including a pragmatic appreciation of its uncertainty.

Risk managers, in consultation with risk assessors, should then decide whether the MRA is adequate to proceed further in evaluating MRM options, or whether there are elements that need further risk assessment**.**

6 IDENTIFICATION AND EVALUATION OF MRM OPTIONS

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

6.1 AVAILABLE MRM OPTIONS

At national level, the objective of MRM options evaluation is to identify the option or options that can control a microbiological hazard to a degree that will achieve the ALOP. In the case of Codex, the evaluation of MRM options will typically follow two phases, the selection of the type of guidance that will be developed and the identification of specific recommendation and practices within that guidance document. Where there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the CAC should not proceed to elaborate a standard but may consider elaborating a related text such as Code of Practice, provided that such a text would be supported by the available scientific evidence[15].

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

There are generally a number of different viable options. In general, any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level can be considered a MRM option. Whenever feasible, both Codex and countries should attempt to focus on specifying the level of control or risk reduction that is necessary (i.e., establish the stringency required of the MRM system). Examples of MRM options that Codex and countries alike may wish to consider for application either alone or in combination are provided in **Annex II**.

6.2 COMMUNICATING THE STRINGENCY OF MRM SYSTEMS

Historically, different approaches have been used to establish and communicate the degree of stringency required of MRM systems, but until recently it has not been possible to directly relate these requirements with anticipated public health outcomes beyond general qualitative considerations. The increased adoption of risk analysis as a framework for food safety is allowing more quantitative and transparent approaches for relating ALOPs to MRM system stringency and the comparison of MRM options for equivalence. This has allowed the development of new MRM tools such as Food Safety Objectives (FSOs), Performance Objectives (POs) and Performance Criteria (PC) and enhancement of the scientific basis of existing MRM tools such as Microbiological Criteria (MC).

[15] Statement adopted by the 24th Session of the Commission (ALINORM 01/41)

Recognizing the difficulty of relating control measures directly to an ALOP, the concept of FSO has been introduced to assist in the development of potential MRM options. Conceptually, the FSO can be viewed as the consumers' maximum level of exposure to a microbiological hazard that still achieves the ALOP. As such, a FSO articulates the overall performance expected of a food chain in order to reach a stated or implied public health goal. The overall performance results from the level of control achieved by the food safety systems deployed from "farm to fork".

Effective MRM typically requires that additional risk-based milestones be established that articulate at different stages the degree of stringency a MRM system must achieve to ensure the ultimate food safety outcome. As a means of addressing this need, two related terms, PO and PC have been introduced. The purpose of a PO is to articulate the maximum frequency and/or concentration of a microbial hazard at a particular stage in the food chain that should not be exceeded in order to still achieve the FSO. How the required PO can be achieved is then articulated through PCs, which specify the desired effect in the frequency and/or concentration of a microbial hazard(s) by one or more control measures.

6.2.1 Food Safety Objective (FSO)

FSOs are established by the competent authority. FSOs are seldom verifiable as regulatory standards as they occur at the time of consumption. They will generally need to be translated by the competent authority and/or food businesses to PO, PC, or microbiological criteria (MC) at earlier stages in the food chain.

Examples of hypothetical FSOs are:

- the level of *L. monocytogenes* in ready-to-eat foods (i.e. for foods that are not cooked just prior to consumption) does not exceed 100 cfu g^{-1} ,
- the concentration of salmonellae must be less than 1 cfu per 100 kg of milk powder,
- the frequency of *S. enteritidis* in eggs does not exceed 1 egg per 100,000.

In countries FSOs can be used:

- to translate the ALOP (whether explicit or implicit) into a more useful parameter for interested parties, and where required to encourage change in operational food safety management, or in the behavior of consumers, in order to enhance the safety of certain products,
- for communication to parties involved in food trade: established FSOs may not be universally common and will take into account national and regional situations**,**
- by the food businesses to design their operational MRM system, i.e. through selecting appropriate PC and control measures, taking guidance from PO when these have been established.

6.3.2 Performance Objective (PO)

The frequency and/or concentration of a hazard at specified stages in the food chain can differ substantially from the FSO.

- If the food is likely to support the growth of a pathogenic microorganism between the point of the PO and consumption, then the PO will necessarily have to be more stringent than the FSO.

- If the food will receive a treatment that inactivates or reduces the level of a microbiological hazard after the point of the PO (e.g., cooking by the final consumer), then the PO may be less stringent than the FSO. Nevertheless, as some raw products can be a source of a contamination for other ready-to-eat foods, the goal in some cases could be to establish a PO just prior to the point of consumer handling rather than relying solely on an FSO. In that case, the PO and the FSO could be the same (e.g. *Campylobacter* on raw poultry, *Salmonella* on raw foods of animal origin).

- If frequency and/or concentration of the microbiological hazard is not likely to increase or decrease between the point of the PO and consumption, then the PO and the FSO could be the same.

A MRA can assist in determining such relationships.

As indicated earlier, FSOs will be typically established by countries. Countries may also establish POs. In the absence of nationally established POs, food businesses may find it beneficial to establish a PO. In general, a PO intended at a specific step in the food chain for a product that is delivered from one establishment to another for further processing is established taking into account knowledge such as (i) the probability and extent of growth under specified storage and transport conditions and (ii) the requirements of the other establishment to enable it to meet the PO for the further processed product.

For a ready-to-eat food, a PO established at the end of the manufacturing process takes into account knowledge of (i) the probability and extent of growth under specified storage, transport and distribution conditions, (ii) the expected or specified shelf life, and (iii) the expected changes in hazard levels during preparation by the consumer. Shelf life relates to the period during which the food maintains its microbiological safety at a specified storage temperature and, where appropriate, specified storage conditions. When establishing shelf life, it should be demonstrated that the level of hazard can be kept within the FSO throughout the maximum period specified, under reasonably foreseeable conditions of distribution, storage and consumer handling. Shelf life determination can be carried out by the food business by testing products subjected to the storage conditions specified or by predicting microbial growth in the product under the specified storage and distributions conditions. Reasonably foreseeable conditions of temperature storage should be integrated into the study or be taken into account e.g. by applying an appropriate safety factor, by shortening the maximum durability specified in the labeling or by requiring lower storage temperatures.

POs are generally not intended to be verified by analytical means. However the compliance of products with a PO should be surveyed or monitored by screening programs.

POs, unlike FSOs, are intended to be measurable and verifiable. This would typically be done by the establishment of a MC that would provide a statistically based means for verifying within a stated degree of confidence that the PO is not being exceeded. Where the measurement of levels of microbiological contamination is not practical, verification could be alternatively achieved through the statistically based monitoring of pertinent process parameters or product parameters.

6.2.3 Performance Criterion (PC)

PC is established by the food business. The PC can be expressed, for instance, in terms of a desired reduction (or acceptable increase) in the concentration of a hazard in the course of a particular control measure, e.g. the result of a particular treatment.

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, whereas 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.

Ideally, PCs at individual steps of the food chain are predetermined and validated[16] such that there is a sufficient confidence in the design of the food safety control system at individual steps (i.e. validating that POs are met by the respective PCs) as well as regarding the overall food chain (i.e. validating that the FSO is met).

6.3.3 Microbiological Criterion (MC)

Consequential to the introduction of the concepts of FSO/PO, the role of MC will expand. Currently, MC are used as a control measure to assess the safety of a specific lot or consignment of food/feed when there is no information available on how or under what conditions the food/feed was produced (i.e., separate safe from unsafe). Of course there will continue to be the need for this application, but MC will increasingly focus on verifying the continuing effectiveness of all or part of a food safety control system. As such, the primary role

[16] See "*Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures*" agenda item 9 (CX/FH 04/9)

of MC is to provide objective means of verifying at a specified level of confidence that a PO or PC (or a FSO) is being met.

The sampling and statistical designs employed for process control validation and verification[17] often differ substantially from those used for "attributes" or "variables" testing of individual lots of food. Moreover, they depend on the type of hazard, the level of confidence required, the "defect" level (the frequency and/or level of the hazard deemed unacceptable), and the extent of knowledge available of the food being evaluated. For the purpose of system validation, monitoring and 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 regarding the management of the hazard within the specific food safety control system, and the statistical methods being employed.

In general, a MC will have to be more stringent that 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. MC may be based on the measurement of related parameters (e.g. indicator microorganisms or products of microbial metabolism). However, care must be taken to ensure that the basic assumptions underlying the selection of the surrogate parameter are scientifically valid (e.g., assumption that the presence and extent of contamination of a food with *Escherichia coli* is directly related to the extent of fecal contamination).

7 SELECTION OF MRM OPTIONS AND IMPLEMENTATION OF MRM DECISIONS

7.1 SELECTION OF MRM OPTIONS

In selecting acceptable MRM options, the protection of human health should be the primary consideration.

The selection of MRM options lies with countries, however, in the development of its guidance documents Codex considers a variety of MRM options, recommending those that it concludes are feasible and effective.

The selection of MRM options that are both effective and practical will generally involve consideration of the following:

- MRM systems designed to prevent hazards (e.g., HACCP) are more effective than those based on detecting and correcting food safety system failures (i.e., traditional microbiological testing programs);
- The complete food chain from primary production (including feed) to consumption should be considered in relation to potential risk mitigation strategies, though the selection of practical MRM options may effectively focus on specific segments of the food chain;
- Other potential sources of the hazard and/or possible other product types to which the population may be exposed;
- Choices of MRM approaches that can be used to meet the required level of stringency should to the greatest extent feasible be consistent with fostering technological innovation that lead to new means for enhancing food safety;
- The best available scientific and technical knowledge of the microbiological hazards and the understanding of the primary production, processing technology and handling during food preparation, storage and transport;
- Other factors[18] such as technical and economic feasibility for the impacted food/feed industry, or consumers' perceptions;
- The country's legal and regulatory structure to ensure that MRM options are enforceable, including verification of efficacy;

[17] See "*Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures*" agenda item 9 (CX/FH 04/9)
[18] See Procedural Manual, 12 Th edition p165: criteria for the consideration of the other factors (…)

- The diversity of production methods and processes, inspection, monitoring and verifications systems, sampling and testing methods, distribution and marketing systems, and consumer use patterns associated with the food;
- The level of protection deemed appropriate by risk managers (ALOP), considering all interested parties preferences relevant for the health protection of consumers, and the results of the cost-benefit analysis;
- Uncertainties and the corresponding commitment to the research and evaluation that will eliminate these uncertainties within a reasonable time frame.
- Amenability for continued improvement and self-correction during subsequent implementation.

7.2 IMPLEMENTATION OF MRM DECISIONS

Implementation of MRM decisions, including Codex MRM options adopted at national or regional level, is carried out by countries. When selecting MRM options, competent authorities should be able to provide recommendations on their implementation by food business.

8 MONITORING AND REVIEW OF MRM DECISIONS

An essential part of a MRM framework is the on-going gathering, analyzing, and interpreting of data to determine how well MRM decisions have performed and to determine what steps may need to be taken to achieve continual improvements in public health. Acquisition of public health surveillance data and related evaluation of the incidence of pathogens in foods at a national, regional or international level allows MRM strategies and food safety measures to be appropriately reviewed in relation to stated public health goals. These analyses are important for further refining MRM programs and for evaluating new food safety problems.

8.1 MONITORING

Monitoring is in most cases the responsibility of national competent authorities, for instance when surveillance of human populations and the analysis of human health data are used. International organizations such as the WHO provide guidance for establishing and implementing public health monitoring programs.

Monitoring is used to provide information on risks to human health from specific hazards and/or foods. In this respect, surveillance of human populations includes investigation of foodborne disease outbreaks and trace-back to the source of the likely causal pathogen.

Examples of monitoring are national and international databases of foodborne diseases, systematic investigation of foodborne disease outbreaks, and integrating data on human foodborne diseases with data on hazards in the food supply (e.g. the prevalence of infected animals at the level of primary production).

Of relevance are also food-intake and consumption databases and other tools that give insight in consumption patterns, which is essential information in exposure assessment.

Where relevant, existing national monitoring and surveillance activities should be re-designed to include collecting data relevant to MRA or to collect data in an improved format that makes the current data collected suitable for use in MRAs. Improvement of data collection is key to support MRM decision-making.

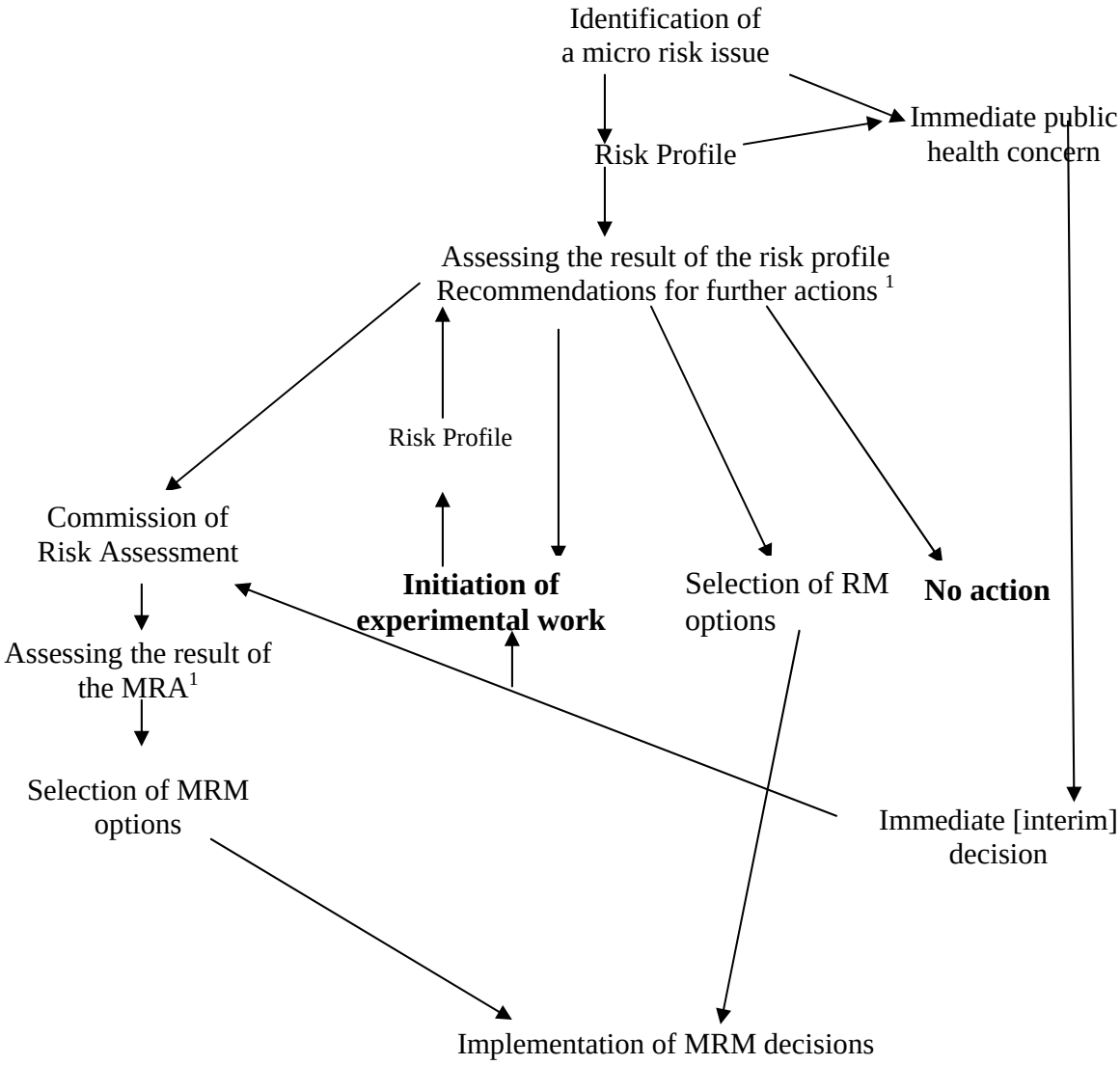
8.2 REVIEW

Reviews may change the MRM decision taken. The results of reviews and the associated consequences or actions that risk manager considers to take should be made public and communicated to interested parties.

Planning periodic review of MRM strategies and options is the best way to assess whether or not the desired results are achieved and the projected contributing to consumer protection is delivered. On the basis of incidents, recalls, epidemiological studies or other events, a decision may be taken that review of a particular MRM option is necessary.

Industry and other interested parties (e.g., consumers) can suggest the review of MRM options as it is required to respond if human health data shows inadequacy of such options. Evaluation of the success of MRM options in industry may include reviewing the effectiveness of HACCP and its pre-requisite programs, product analytical testing results, and the incidence and nature of product recalls and consumer complaints.

Review of MRM decisions should also be necessary when new MRM options or new information becomes available. New data that typically might alter the outcome of a MRA, and thus the implemented MRM options chosen on the basis of this MRA, substantially include new information on hazard virulence, prevalence and concentration in foods as well as new information on the sensitivity of (sub)-populations and changes in dietary intake patterns.



Examples: Issue guidelines, issue standards, mandatory criteria, ban the product, educate the consumers, articulate ALOP, establish FSO, advise on or establish PO, advise on control measures/PC

Monitor & review of MRM decisions

[1] *Where appropriate the assessment should be related to an ALOP*

ANNEX I: OVERALL FRAMEWORK FOR MANAGING FOOD-BORNE RISKS

This figure depicts the flow of possible activities within MRM process once an issue has been identified. Risk managers (RMs) identify a microbiological risk issue that may impact on public health. As an initial activity, RMs compile a risk profile in which they log their current insight in the issue in a concise fashion, formulate their opinion on priority and urgency to deal with the risk issue and record the brief for any MRA to be commissioned. In judging their opinion, RMs should consider explicit or implicit food safety policy (e.g. public health goals, already established relevant ALOPs).

On the basis of the risk profile, risk managers may decide not to commission a MRA, either because the risk issue is not serious enough to warrant intervention or because the risk issue is very serious and requires immediate intervention. In the former case, the MRM activity seizes. In the latter case, RMs may decide to select and implement specific MRM options (a number of which are indicated in the Figure) without any further attempt to gain more insight in the risk issue. Implemented options will be analyzed and reviewed to assess adequacy of the intervention. For Codex, the CCFH should ensure that the conclusion of the MRA is presented before making final proposals on the available MRM options.

When RMs decide to commission an MRA, they will have to clearly brief the risk assessors regarding the scope, timeline and possible intervention scenario's to be considered in the MRA and on the pertinent RMs questions to be answered. In the course of conducting the MRA, which often is an iterative process between RMs and RAs, the status of the insight in the risk issue could urge RMs to intervene in the risk issue without further ado.

After the MRA has been completed, the results need to be shared by the RAs with RMs and other interested parties, whereas the possible interventions need to be discussed in good detail with all relevant stakeholders. In the case that an ALOP is not already available, it is up to the discretion of the RMs to decide whether it is appropriate for the risk issue at hand to establish a formal ALOP or to formulate a different type of public health goal. As depicted in the Figure, articulating an ALOP is one of many more MRM options.

When articulated, the ALOP or public health goal needs to be translated into a metric that provides meaningful guidance for the food safety system functioning at the operational level in the food chain. RMs may establish an FSO to communicate the hazard level that they would expect <u>not</u> to be surpassed at the moment of consumption within the relevant food chain. Such an "end-of-chain" value can then, when appropriate, be translated into guidance [/milestone] values earlier in the food chain (Performance Objectives). Meeting the FSO and PO will rely on implementing the correct control measures along the chain, which may be governed by Performance Criteria (PC).

The success of the interventions decided on, and put into actions through the respective control measures, should be evaluated and reviewed on a regularly basis. New data, knowledge and the progression of technical capabilities may lead RMs to decide that an amendment of the interventions and thus of the [suite of] control measures in the food chain is called for. RMs should then update and revise the existing study and communicate the outcome to all interested parties.

ANNEX II : EXAMPLES OF AVAILABLE MRM OPTIONS

1) For application by countries:

- establishing regulatory requirements and/or creating incentives for introduction of specific MRM tools (e.g. Good Agricultural Practices, Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), HACCP or HACCP-like tools, product tracing systems) or for changes in attitudes in food preparation, handling and use that will likely contribute to risk reduction in exposure to hazards
- establishing public inspection schemes, certification and approval procedures;
- carrying out educational and/or information programs to the population at large and/or affected sub-groups about steps they can take to reduce their exposure to hazards;
- setting establishing FSOs for ready-to-eat foods in general, or for specific groups/types of food;
- advising on maximum levels of specified hazards (POs) tolerable at specified stages in the food/feed chain where such levels generically apply and are of critical importance to the overall chain performance;
- establishing control measures, such as Codes of Practices or PC specifying "safe harbour" or "default" measures for such parties that do not have the means to establish appropriate measures themselves or who elect to adopt such control measures;
- prohibiting foods/feed with a substantiated history of contamination or toxicity;
- requiring import certificates for certain products;
- carrying out public inspection/audit procedures and promulgating awareness, education and training programs to enforce or stimulate that:

– prevention of contamination and/or introduction of pathogens is addressed at all relevant stage in the food/feed chain including reduction in the level of specific pathogens in primary production;

– prevention of growth of pathogens is obtained by the combined action of extrinsic factors (e.g. chilling or freezing) and/or intrinsic factors (e.g. adjusting pH, a_w; adding preservatives; employing microbiological competition);

– pathogens are destroyed (e.g. cooking, irradiation);

– procedures for rapid recall of food are in place, including appropriate traceability/product tracing for effectiveness;

– products are labeled properly with consumer information regarding additional guarantees of safety or that information is provided that either instructs regarding safe handling practices or warns regarding microbiological hazards that are likely to occur and for which adequate controls were unavailable;

2) For application by Codex:

- establishing principles and guidelines for food hygiene, for the application of the HACCP Principles, for the establishment and application of PO, PC and MC for the validation of MRM systems for control measures and for the design of monitoring and verification procedures, etc.; and its prerequisite programs (GMP, GHP), which either apply generically or are targeted at specified commodities and/or microbiological hazards)
- recommending FSOs in general or for specific foods, where appropriate;
- establishing principles and guidelines for public inspections procedures, export certification, etc.