codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)
(at Step 3 of the Procedure)

Prepared by France with assistance of Argentina, Australia, Austria, Belgium, Canada, China, European Commission, Denmark, Finland, Germany, Hungary, India, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Sweden, United Kingdom, United States, ICMSF 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*) **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 Syed.Ali@fsis.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 1 February 2005**.**

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 microbial hazards for foods in international trade.

Since that time, a lot of work has been done and successive papers have been examined by the Committee each year, most recently at the 36th Session in Washington DC (March 29th - April 3rd, 2004). The CCFH discussed document CX/FH 04/6, decided to forward to the CCGP for endorsement the agreed definitions on Food safety objective, Performance objective and Performance criterion and provided specific points to be further considered by the group. It was suggested that new work was required, in particular to articulate more clearly the applicability of the document, and better describe how different provisions could be applied by the Codex and/or by Governments; to review some of the general principles; to clarify the concept on regional differences; to provide clearer explanation on various options for microbiological risk management (MRM) and to simplify the flow chart on the overall framework for MRM.

It was agreed that the drafting group would revise the document at step 3 for circulation, comments and further consideration at the 37th Session of CCFH.

REVISED DOCUMENT

The previous document has been redrafted according to the discussions of the drafting group held in Brussels (September 29th – October 1st, 2004)[1], and further electronic consultations. The main modifications are:

- Section 2 (Definitions): proposal of a new definition: risk manager;
- Section 3 (general principles for MRM): proposal of eight short principles;
- Section 4 (ALOP): has been deleted. The new section entitled "General considerations" explains why those 8 principles are relevant; the concept of ALOP is presented now as a general consideration;
- Section 6 (identification and evaluation of MRM options): has been reorganized with Annex III that has been included in the text; the title of this section has been renamed: "Identification and selection of MRM options". A new Annex III presents three examples of the use of the new concepts: FSO, PO, PC, process and product criteria, for the hazard *Listeria monocytogenes* in ready-to-eat foods.
- Section 7 (selection of MRM options and implementation of MRM decisions): has been renamed "Implementation of MRM options";
- Section 8 (monitoring and review) has been modified in order to take into account comments presented during the meeting of the working group .

The working group has developed a framework on the MRM process that takes into account the definition of the term "**Risk Management**" existing in the Procedural Manual of the CAC[2]. Nevertheless, although the responsibility for MRM lies with Codex and governmental organizations, industry is responsible for implementing the MRM options selected and for ensuring the safety of products by application of a continuum of effective control measures, as explained in Section 7.

RECOMMENDATION

The Committee is invited to discuss 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: Austria, Belgium, Canada, European Commission, Denmark, Finland, France, Germany, India, Ireland, New Zealand, Norway, Sweden, United Kingdom, United States, WHO, ICMSF and IDF. Written comments were sent by Australia.

[2] **Risk management** is defined as "the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and others factors relevant for the health protection of consumers and the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options"

Appendix

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INTRODUCTION

Diseases caused by foodborne microbial hazards[3] 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, changes in human demographics and behavior, international travel and trade. The globalization 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 a 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 ensure the protection of consumers, while facilitating the judgment of equivalence of food safety control systems.

In this document, a four-step process involving (1) preliminary microbiological risk management (MRM) activities, (2) identification and selection of MRM options, (3) implementation of MRM options, and (4) monitoring and review of MRM options is described.

This document should be read in close conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[4] and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment[5]. Countries, organizations and individuals involved with MRM are encouraged to utilize these 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 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 conduct of MRM intended for use by Codex and countries, 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 should also be useful for **industry**[6] and other interested parties who are involved in MRM on a day-to-day basis.

2. DEFINITIONS

The definitions of risk analysis terms related to food safety incorporated in the procedural manual of the CAC, 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, risk assessment policy, risk profile, risk estimate, food safety objective (FSO), performance objective (PO), performance criterion (PC), product tracing/traceability and equivalence.**

The definitions from *The Guidelines for the Application of the HACCP System*[7], e.g. **control measure, step** or **critical control point**, the definition of a **microbiological criterion** included in *The Principles for the*

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

[4] 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 04/27/33A)

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

[6] 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*).

[7] Annex to CAC/RCP 1-1969 rev 3 (1997), revised by 26th session of the CAC

Application of Microbiological Criteria for Food[8], and the definition of **interested parties** included in *The Working Principles for Risk Analysis for Application in the Framework of the Codex*[9] 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*[10].

Risk manager is defined as follows: a national or international governmental organization with responsibility for MRM.

Note: it is realized that the definition of Risk Management does not include the implementation step and that various aspects of MRM are considered and implemented by industry and other interested parties, but risk managers would only be associated to governmental organizations with authority to decide on the acceptability of risk levels associated to foodborne hazards.

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 should be the primary consideration in MRM.
- PRINCIPLE 2: MRM should take into account the whole food chain.
- PRINCIPLE 3: MRM should follow a structured process.
- PRINCIPLE 4: MRM should be transparent.
- PRINCIPLE 5: Risk managers should ensure effective consultation with relevant interested parties.
- PRINCIPLE 6: Risk managers should ensure effective interaction with risk assessors.
- PRINCIPLE 7: MRM should take account of risks resulting from regional[11] differences in hazards in the food chain.
- PRINCIPLE 8: MRM decisions should be subject to review and revision.

4. GENERAL CONSIDERATIONS

Codex and government decisions and recommendations should 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, taking into account relevant ecological and environmental conditions, primary production (including feed), product design and processing, transport, storage, distribution and handling practices used throughout the food chain, including imported products.

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.

The MRM process should be transparent. Risk managers should articulate and implement uniform procedures and practices to be used in the development and implementation of MRM programs, the determination of MRA policy, establishment of MRM priorities, allocation of resources (e.g. human,

[8] See CAC/GL 21 - 1997
[9] see ALINORM 03/41
[10] document CX/FH 04/9
[11] see CX/FH 98/13 on the meaning of the word "regional"

financial, time) and determination of the factors[12] to be used in the evaluation of MRM options. They should ensure that the options selected are scientifically justifiable, proportionate to the risk identified and not more restrictive of trade or technological innovation than required to achieve the ALOP. At the national level, risk managers should ensure that decisions are enforceable, including verification of efficacy.

Since various aspects of MRM are implemented by industry and other interested parties, risk managers should ensure an effective and timely consultation with all relevant interested parties. 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.

Acceptable risk levels for 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 effects.

MRM should be a continuous process and decisions made should be subject to timely review, taking into account all relevant newly generated data.

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 manage the associated risk. At the start of this process, the food safety issue should be clearly identified and communicated.

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

Some food safety issues may require that an immediate decision 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 action when there is an immediate public health concern and when they have to face up to a crisis situation.

[Where scientific knowledge is insufficient, it may be appropriate to apply a precautionary approach through provisional decisions[13]]. Whenever possible, the timeframe or circumstances under which the [provisional]

[12] see procedural manual, 12th edition p.165: *criteria for the consideration of the others factors (…)*

[13] see the draft *working principles for risk analysis to be applied by countries*, under consideration by the CCGP (see ALINORM 04/27/33A)

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 decision making tool that, in a concise form, presents 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. 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

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*. It is 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 outputs of the MRA should be presented by risk assessors in such a manner that they can be properly understood and utilized 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 of the MRA study as conducted, 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 if some elements of the MRA need further study.

6. IDENTIFICATION AND SELECTION OF MRM OPTIONS

6.1 Identification of the available MRM options for Codex and countries

The risk manager needs to identify and select MRM options that will subsequently be implemented 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.

Where there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the CAC does not proceed to elaborate a standard but can consider elaborating a related text such as Code of Practice, provided that such a text would be supported by the available scientific evidence[14].

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 or HACCP-like tools, traceability/product tracing systems;
- 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;
- introduce standards such as POs, PCs and MCs at specific stages in the food/feed chain where the need is of critical importance to the performance of the overall chain;
- establish control measures specifying "safe harbor" 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 marketing of foods/feed with a documented history of contamination or toxicity;
- establish requirements for public 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;
  - properly labelling with consumer information that either instructs regarding safe handling practices;

6.2 Selection of MRM options

The primary responsibility for selecting appropriate MRM options lies with the risk manager. In any case, 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.

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

- 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 reviewed and revised during subsequent implementation,

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

- the capacity of the food businesses to manage food safety (e.g. human resources, size, type of operation). For instance, a more traditional "safe harbour" approach may be selected for small and less developed food businesses, rather than an FSO driven approach (see below)

Where available, an MRA can often help in the evaluation and selection of MRM options. 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).

Historically, different approaches have been used to establish and communicate the degree of stringency required of food safety control systems, but until recently it has not been possible to directly relate these requirements with anticipated public health outcomes beyond general qualitative considerations. 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"), 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.

Conceptually, an FSO is derived from the ALOP, whereas a PO or a PC is derived from an FSO. However, in the absence of an FSO, the concepts of PO and PC may be applied as needed to establish process requirements. An MRA can help in choosing the best step where to apply control measures, and hence deciding upon the need for any of these tools.

The concepts and interrelationships of FSO, PO, PC and MC are further explained below.

Annex III provides examples of their use.

6.2.1 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 industry 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 dose-response curves linking hazard levels to disease incidents (risk characterization). 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 behavior of consumers, in order to enhance the safety of certain products,
- for communication to parties involved in food trade. Notably, FSOs may not be universally common and may take into account regional differences**,**

- 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).

6.2.2 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 rules 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 (e.g. through validation) 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;
- 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 could theoretically 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 to a proposed PO/FSO. This knowledge can be the basis for considering a margin of safety in the PO/FSO level. In designing their food safety control system such that PO and FSO (set by government or chosen by industry itself) are met, industry will have to make provisions in accord to their ability to consistently meet these standards in operational practice.

Industry 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, …). Where the same food is marketed in different countries where different levels of protection (e.g. articulated as FSOs) apply will also impact the POs. Countries may establish generic POs for a type of food, where these conditions of the subsequent steps in the food chain are generally uniform and/or advice to food businesses that are not capable of establishing POs themselves.

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).

6.2.3 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 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 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 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 PC are often translated by industry or sometimes by competent authorities, into **process criteria**[15] 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 recognized and used by industry and competent authorities.

6.2.4 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. However, MC may also find utility to verify the continuing effectiveness of all or part of a food safety control system. 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, and the statistical methods being employed.

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 fecal 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 organizations

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 organizations, e.g. FAO and WHO, and developed countries in the spirit of the SPS Agreement.

[15] 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."*

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.

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 comply. 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 finalizing 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;
- Design and implementation of appropriate combinations of validated control measures, including the identification of PC;
- Monitoring and verification of the food safety control system or relevant parts thereof (e.g. control measures, good practices)
- Development of plans for corrective actions, that may include withdrawal/recall procedures, traceability/product tracing systems, 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 are responsible for adhering to food safety-related instructions (e.g. public education programs, safe handling labels, date labels, prevention of cross contamination).

8. MONITORING AND REVIEW OF MRM OPTIONS

8.1 Monitoring

An essential part of the MRM process is the on-going gathering, analyzing, and interpreting of data, in this context referred to as monitoring. Monitoring is the basis on which the risk manager evaluates how well MRM options perform, and may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the status of public health.

Monitoring respecting public health is in most cases the responsibility of national governments, for instance when surveillance of human populations and the analysis of human health data are used. International organizations 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;
- laboratory-based surveillance of hazards isolated from humans, plants, animals, foods, and food processing environments; environmental health data on practices and procedures;
- behavioral risk factor surveillance of food worker and consumer habits and practices.

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

- A public health surveillance system should be able to estimate the proportion of illnesses and death that is truly foodborne and the major food vehicles, processes, and food handling practices responsible for each hazard;
- Interdisciplinary teams of epidemiologists and food safety experts should be formed to investigate foodborne illness to identify the food vehicles and the series of events that lead to illnesses;
- Microbiological and/or physicochemical indicators of a particular intervention should be considered together with human disease data to evaluate programmatic impact on public health;
- Countries should work towards harmonization 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 could be established as part of the implementation plan. Review may lead to a change in the MRM option(s) selected and implemented.

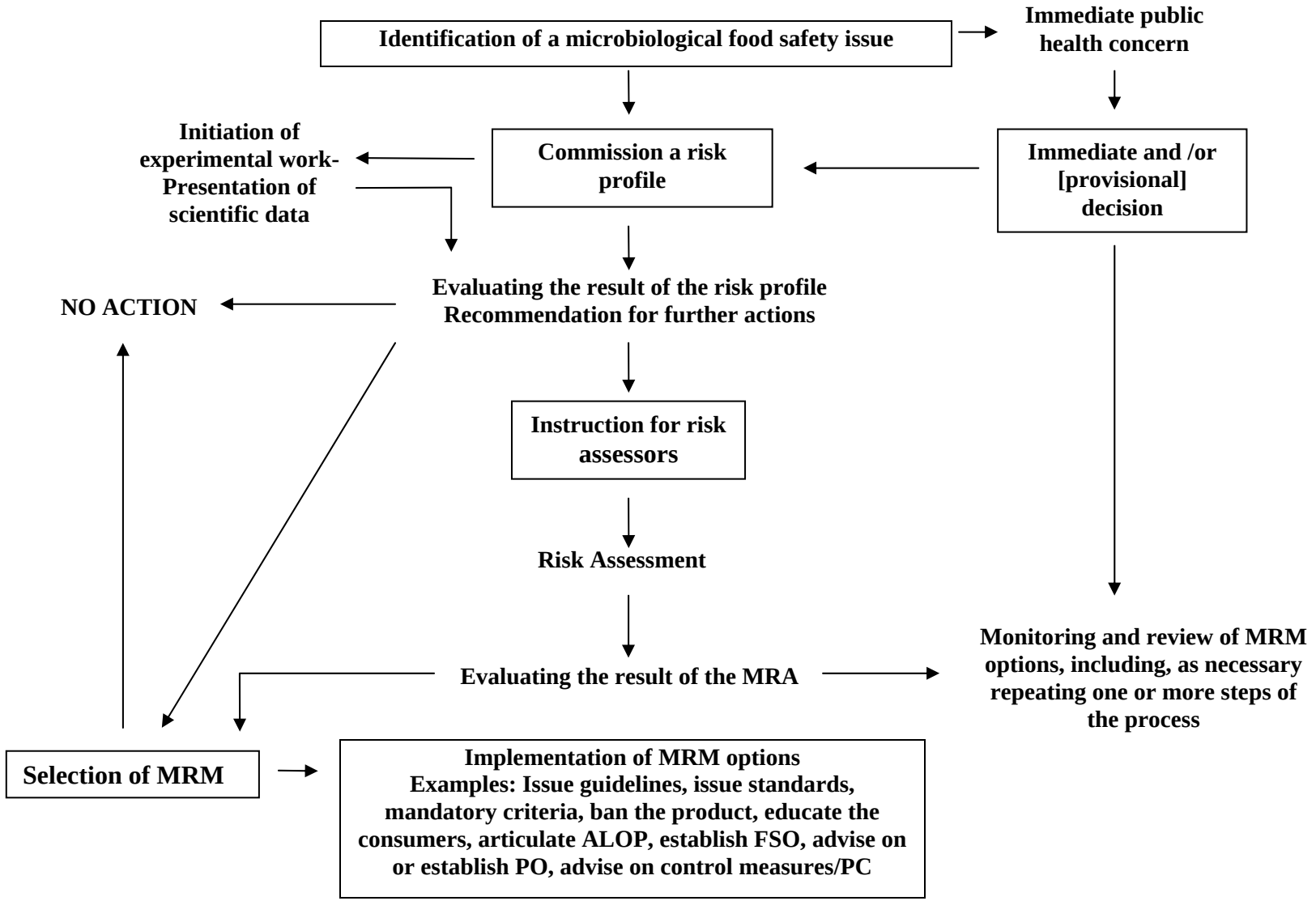
Planning periodic review of MRM options is the best way to assess whether or not the expected consumer protection is delivered. On the basis of a review of the information collected through the various appropriate monitoring activities, a decision may be taken to amend the MRM option implemented or to 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 I: Overall framework for managing foodborne risks



ANNEX II: SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK PROFILE

PURPOSE:

The risk profile is an abbreviated discussion paper that lays out the key elements of a MRM concern in order to facilitate decision-making on the part of the risk manager in relation to the need and scope of newly proposed work.

SCOPE AND RATIONALE:

Identify the food safety issue (microbial hazard(s) / commodity(commodities) of concern) and provide information required by the risk manager to make an informed decision on the need to undertake work on the subject.

RISK PROFILE ELEMENTS:

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.
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 hospitalization)
        - Nature and frequency of long-term complications
        - Availability and nature of treatment
        - Percentage of annual cases attributable to foodborne transmission
    - Characteristics of the foodborne transmission:
        - Epidemiology and etiology of foodborne transmission, including characteristics of the food or it use and handling that influences foodborne transmission of the hazard
        - Foods implicated
        - Frequency and characteristics of foodborne outbreaks
        - 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)
- 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 (organizations, 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 - EXAMPLES OF THE USE OF FSO, PO, PC, MC, PROCESS AND PRODUCT CRITERIA

1. Pasteurized perishable product :

The safety of the product will be based on the following:

- Use of a heat treatment as the control measure, with appropriate **process criteria** (the specified time and temperature condition to be achieved by the heat treatment) to consistently deliver the required **PC**, which for pasteurization is, for instance, a 6 log reduction in hazard level. Process criteria for pasteurization can be set by the manufacturer or by the competent authority as a “safe harbor”;
- A suitable shelf life at specified conditions of temperature and time;
- Additional **control measures** to prevent recontamination after pasteurization.

Survival of hazards in the product is too low to be detected by analytical methods unless huge sampling is conducted. Hence setting an **MC** would not provide useful information and will therefore be irrelevant.

2. Raw fermented product kept at ambient temperature in which the hazard can not grow

Product criteria specified for certain control measures (pH, water activity, preservative concentration, etc.) ensure the absence of growth in this ready-to-eat product. No growth of the considered hazard being expected, the end-product **PO** can equal the FSO. Compliance can be verified with a **MC** (provided no recontamination can occur, for example if the product is sliced before sale). Other **MC** should also be established for raw ingredients.

3. Raw product kept at low temperature in which the hazard can grow :

As growth of the hazard is possible between the sale to the consumer and the time of consumption, it is relevant to use a first **PO** at the retail level. This first PO should take account of the potential for growth such that, at the time of consumption, the hazard amount in servings does not exceed the FSO. This first PO can be checked by means of a first **MC** (for the same organism where the first PO is established at measurable levels – otherwise for measurable indicators).

Yet, between the time where the product is put onto the market by the factory and the sale to the consumer, growth is also possible. Therefore another **PO**, stricter than the previous one, should be set by the manufacturer for his end-product. The latter PO could also be checked by a **MC**.

Other **MC** should be set for raw ingredients where appropriate.