codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FH 00/6**
July 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-third Session

Washington, D.C., USA, 23 – 28 October 2000

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, Canada, Denmark, Germany, India, Italy, Netherlands, Japan, New Zealand, Norway, Sweden, United Kingdom, United States of America and ICMSF)

Governments and interested International Organizations are invited to submit comments or information on the attached Draft Code at Step 3 (see Annex) 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 23-24)* **to:** Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, 1400 Independence Avenue, S.W., Washington DC, 20250 USA, Fax: 1 (202) 720-3157, or email: uscodex@usda.gov with a copy **to:** Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, viale delle Terme di Caracalla, 00100 Rome, Italy, by Fax. +39 (06) 5705.4593 or email:Codex@fao.org **before 10 September 2000**.

BACKGROUND

The Codex Committee on Food Hygiene (CCFH) at its 29th Session (1996) agreed that new work should be initiated to develop recommendations for the management of microbiological hazards for foods in international trade. The 22nd Session of the Codex Alimentarius Commission approved this new work. The Committee, at its 30th Session, considered a paper on *Recommendations for the Management of Microbiological Hazards in Foods in International Trade* and agreed that this paper should be further developed by France with the assistance of Argentina, Australia, Canada, Denmark, Germany, India, Italy, Japan, New Zealand, the Netherlands, Norway, the United Kingdom, the United States and the ICMSF.

The 31st Session of CCFH considered the revised paper and agreed that its title be changed to *Principles and Guidelines for Microbiological Risk Management*. The Committee also agreed that concepts regarding the regional prevalence of foodborne pathogens presented in the paper *The Implications of Regional Differences in the Prevalence of Foodborne Pathogens in the Management of Microbiological Hazards for Foods in International Trade* be incorporated into this document on microbiological risk management.

The 32nd Session of the Committee further considered the draft principles and guidelines. Significant discussion occurred on the structure of the document, on the relationship between risk management and risk assessment, on the use of precaution, and on need for flexibility with respect to the use of the draft principles and guidelines by developing countries. As the proposed draft had not yet been circulated for comments in view of time constraints, the Committee agreed to circulate it at Step 3 for comments for further redrafting by France with the assistance of a Drafting Group and consideration by the Committee at its next Session.

REVISED DOCUMENT

This document has been modified according to discussions of the working group and has taken into account the following documents :

– *Report on a Joint FAO/WHO Expert Consultation on Risk Management and Food Safety, Rome, 1997*

– *Conference Room Documents 6 (Finland), 15 (Latin American Poultry Science Association) and 17 (Consumers International)*

– *ALINORM 99/37, para. 70 (23rd session of the Codex Alimentarius Commission)*

– *ALINORM 01/13, paras 91–101 (32nd session of the CCFH)*

– *ALINORM 01/33, Appendix III (15th session of the CCGP)*

– *Comments received since the 32nd session of the CCFH (ICMSF, USA, Canada)*

Furthermore the document's layout has been modified according to comments of certain delegations (New Zealand, WHO) at the 32nd session of the Codex Committee on Food Hygiene) who pointed out that this document did not match the recommendations of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety (Food and Nutrition Paper No 65, Rome 1997).

These principles and guidelines on microbiological risk management should be considered and interpreted in the light of the current deliberations on risk analysis in other Codex Alimentarius committees and in particular the Committee on General Principles (CCGP), which has been instructed to draw up "Working Principles for Risk Analysis" (Document ALINORM 01/33) for incorporation into the Procedural Manual.

The working group tried to make progress on the subject of Food Safety Objectives; the present section 5.2.2.1. offers a new version employing the use of a new term *Microbiological Food safety Objective* (MFSO).

Concerning the precaution principle, the CCGP concluded that the application of this principle needed additional discussion. This commitee also agreed that two alternative proposals (see ALINORM 01/33,

para. 46 and Appendix III, para. 34) would be circulated for comments and that a drafting group would work by electronic mail in order to prepare a revised text based on these comments. These two proposals are provided in annex I of this draft.

To take into account of this situation, the working group agreed to adopt the following procedure :

- to indicate to the CCFH general discussions of CCGP about precaution principle,
- to keep in square brackets the paragraph concerning precaution principle,
- to suggest to CCFH, either to examine during the next session how this principle is used in the context of microbiological risk management, or to prepare a circular letter requesting the members of CCFH to illustrate in a concret way, how precaution is or might be used in the context of microbiological risk management.

RECOMMENDATION

The Committee is invited to review the attached Draft Proposed Principles and Guidelines for Microbiological Risk Management with a view towards its further development, in particular to progress this document to the step 5.

APPENDIX I

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

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INTRODUCTION

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

The increased globalisation of trade in foodstuffs increases the challenge to effectively manage risks arising from microbiological hazards. Risk analysis, including its component parts of risk assessment, risk management and risk communication, can be applied to risks arising from microbiological hazards and should be used as a tool in evaluating and controlling microbiological hazards to help ensure the protection of consumers.

Effective control of risks arising from microbiological hazards is technically complex. Countries and individuals involved with microbiological risks analysis, including microbiological risk management are encouraged to review and utilise the guidelines presented in this document as well as technical information in the field developed by the *World Health Organisation and the Food and Agriculture Organisation of the United Nations* and *the Codex Alimentarius (FAO/WHO Expert Consultation on Risk Management and Food Safety-Paper N°65, Rome 1997*). Additionally, particular reference should be paid to the principles and guidelines for risk analysis.*(Document ALINORM 01/33-Appendix III).*

The following principles and guidelines present the different elements of microbiological risk management, indicating what should be considered at each step of the process. The principles for risk management are intended for application in the framework of *Codex Alimentarius* and also intended to provide advice to public authorities including governments. However, they are useful for risk managers in industry and for other interested parties in order to apply a common framework for microbiological risk management,.

1. SCOPE

These principles and guidelines provide a framework for the management of risks arising from the occurrence of microbiological hazards in foods.

2. DEFINITIONS

The definitions cited here are to facilitate the understanding of certain words or phrases used in this document.

Hazard - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect[1].

[Microbiological Food Safety Objective - A statement based on risk analysis[2] expressing the level of microbiological hazard in a food that is tolerable in relation to an appropriate level of protection.

Microbiological risk: for the purpose of this document, risks concerning the presence in food of bacteria, viruses, yeasts, moulds and algae, parasitic protozoa and helminths, and their toxins or metabolites.

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[1] These definitions are taken from the Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition.
[2] (Canada)

Risk - A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food[1].

Risk Analysis - A process consisting of three components: risk assessment, risk management and risk communication[1].

Risk Assessment - A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization[2].

Risk Assessment Policy – Documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during the risk assessment[1].

Risk Characterization - The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment[1].

Risk Communication - The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk related factors and risk perception among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions[1].

Risk Management - The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed selecting appropriate prevention and control options[1].

3. GENERAL PRINCIPLES

The following principles apply to the conduct of microbiological risk management:

- PRINCIPLE 1: Protection of human health should be the primary consideration in risk management decisions.
- PRINCIPLE 2: Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- PRINCIPLE 3: Processes and decisions should be transparent and fully documented.
- PRINCIPLE 4: Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment. In this respect there should be a clear determination of risk assessment policy before risk assessment commences.
- PRINCIPLE 5: Risk managers should take into account the uncertainty of the risk estimate when making risk management decisions.
- [PRINCIPLE 6: In the case where scientific knowledge on the risks is insufficient, risk management decisions may be adopted on an interim basis as part of a precautionary approach to protect public health.]

- PRINCIPLE 7: Arriving at a risk management decision, should follow a structured process and must include identification of available risk management options and their likely impact on mitigating risk to human health.

- PRINCIPLE 8: Risk management decisions should address the whole farm to table continuum, including imported foods.

- PRINCIPLE 9: Risk managers should ensure that any control measures that are to be implemented are optimal regarding their feasibility and effectiveness and *that th*ey are proportionate to the risks identified.

- PRINCIPLE 10: Risk management *decisions* should be reviewed as new information becomes available.

- PRINCIPLE 11: The efficacy of risk management measures has to be periodically assessed with regard to the risk management goals. These measures have to be reviewed if appropriate.

4. INVOLVEMENT OF STAKEHOLDERS

The involvement of stakeholders (interested parties), in the risk management process is essential in order to ensure a transparent and effective process. Stakeholder involvement provides opportunities for the interactive exchange of information and opinion about risk. It may also contribute to bridging gaps in understanding, to sharing values and perceptions, and to facilitating exchange of information and ideas that enable all parties to make informed decisions;

Stakeholders may include, but not be limited to, governmental bodies, consumer organizations, representatives of the food industry and trade organizations, and representatives of education and research institutions.

Involvement of stakeholders can be implemented in many ways, ranging from public meetings to opportunities to comment on public documents.

The nature, extent, and complexity of stakeholder involvement should be appropriate to the urgency with which the problem must be addressed, the complexity and the uncertainties of the problem, the scope and impact of the decisions to be taken and the potential for the decision to generate misunderstanding or controversy.

The risk management decisions should be fully and systematically documented and available to all interested parties on request, in order to ensure transparency.

5. GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

Microbiological risk management should include the following steps. However, their order may vary considerably from case to case, depending on the problem considered and the state of knowledge.

5.1 INITIAL RISK MANAGEMENT ACTIVITIES

5.1.1 Identification of risk managers

Public authorities play a pivotal role in microbiological risk management. However in many situations, risk management responsibilities should or may evolve among other stakeholders.

At the outset of a microbiological risk management activity, risk assessors and risk managers should be identified.

It is important that there be a functional separation between risk assessment and risk management in order to maintain the scientific integrity of the process and stakeholder confidence, and to reduce any conflict of interest between risk assessment and risk management.

In undertaking microbiological risk management activities, there will be a need for frequent and transparent interaction between risk managers and risk assessors in order to arrive at effective risk management decisions and to take into account developments.

While it is a desirable goal that the persons involved in risk assessment and risk management be different individuals, it is recognized that in many countries risk assessors and risk managers may have dual roles.

5.1.2 Identification of a problem

A microbiological public health problem may already be well recognized or may be a new or latent problem.

Problems may be identified on the basis of information such as presence, prevalence and concentration of hazards in the food chain and in the environment, disease surveillance and monitoring information, epidemiological studies, clinical studies, laboratory studies, production practices including process innovation, lack of compliance with standards, experts opinions and public input.

Problem identification may be performed by a single stakeholder (e.g. the public authority) or be a result of collaboration between different stakeholders.

A formal risk management procedure as described in this document is not necessary to manage food hygiene problems which can be dealt with on a routine basis or managed directly by applying the "Recommended International Code of Practice – General Principles of Food Hygiene" or hygiene codes for specific foods.

5.1.3 Risk profile

Elaboration of a risk profile is essential for effective risk management. Risk profile is a situation analysis used to describe briefly a microbiological food safety problem and its context, actions that may be necessary, whether a risk assessment should be carried out, especially as regard what is known and what is not known.

A typical microbiological risk profile might describe :

- which microbiological hazards are causing the problem and the difficulty in controlling them (nature and size of the problem, etc.);

- the source of the microbiological hazard(s), e.g. from the entire food chain (including imported food), the environment, travel, animal contact and person to person transmission);
- the available prevalence and concentration data from the whole food chain;
- the disease incidence data and the types and severity of the adverse effects;
- which populations may be affected (for example, at risk groups such as the elderly, infants and children, the immuno-compromised, or those whose exposure to the microbial hazard may be increased due to dietary intake; socio-economic status, or other characteristics);
- The consumer perception of the problem;
- What is expected to be at risk (e.g., human health, economic concern);
- The available options;
- The potential consequences of action taken or which might be taken (including preventive measures);
- The distribution of risks and benefits.

5.1.4 Defining goals

The goals for a microbiological risk management activity should be identified as early as possible to guide the rest of the decision-making process and should be primarily aimed at preventing or reducing risks in order to protect human health.

It has to be kept in mind that risk management decisions, without prejudicing human health protection, should, to the extent possible, ensure fair practices in the food trade.

The results of the risk assessment phase and subsequent steps of risk management may lead managers to modify or redefine goals.

Goals of a microbiological risk management should be risk related; they may involve public values; they may be directed by statute, policy or regulatory considerations, or economic constraints. One management goal can be to establish Microbiological Food Safety Objectives (MFSOs) and gain their benefit in implementing risk management decisions.

Resolving the issue of who should be the microbiological risk managers should preferably be done at an early stage, though this may not be evident until the risk management options have been identified.

5.1.5 Scope, range and risk assessment policy

Microbiological risk assessment policy setting is a management responsibility. It serves to protect the essential scientific independence and integrity of the microbiological risk assessment. It should be carried out in full collaboration between risk managers and risk assessors and other interested parties.

Typically, a microbiological risk assessment policy should address the issues of transparency -and "unbiaisedness" in the risk assessment process as well as the issues of clarity, consistency and reasonableness in the risk assessment products. In particular, risk assessment policy should determine the essential elements covered by risk characterisation, the questions to be addressed by risk assessment and

provide documented guidelines for dealing with uncertainties (e.g. application of safety factors), for value judgements or policy choices, and make provisions for apportionment of adequate resources, and for peer review.

5.1.6 Commissioning of microbiological risk assessment

To achieve alignment between the risk assessment process and the needs of the risk managers it is necessary to clearly define the issues that the assessors should address. To this end, the results of effective communication between assessors, the decision-makers and the stakeholders prior to initiating a microbiological risk assessment should include a clear statement of the purpose and scope of the assessment . This statement must ensure that the risk assessment provides the information needed by the risk manager. For example, the scope of the assessment may be limited to a specific product-pathogen pair, and the purpose of the assessment may be to reach a decision on a regulatory proposal regarding the level of a pathogen in a ready-to-eat product to attain a pre-specified level of protection with a high degree of confidence.

Once the purpose and scope of the risk assessment have been defined, the assessment should follow the framework identified by the Codex *Principles and Guidelines for the Conduct of a Microbiological Risk Assessment* (ALINORM 99/13A, Appendix II):

5.1.7 Consideration of the process and the results of the microbiological risk assessment[3]

For the best use of a microbiological risk assessment, managers should be fully informed of the strengths and limitations of the risk assessment. To that aim, communication of the following points with regard to the microbiological risk assessment is important:

- All assumptions should be fully acknowledged and their impact thoroughly considered or recognized.
- All risk characterizations should explicitly address sources of variability and sources of uncertainties.
- Estimates may be a range of risk estimates based on different data and assumptions as judged by scientists rather than the presentation of a single risk estimate. Narratives should accompany risk characterizations and be fully communicated and/or explained to users.
- Risk characterisation may address both the present situation and the range of reasonable options (risk reduction) or possible alternatives (substitution risks). Additionally, it may be helpful for risk characterization to include a discussion on how the specific microbiological risk under consideration compares with other health risks.

5.1.8 Identifying the tolerable [4] level of risk (TLR)[5]

Microbiological risk management options assessment should involve identifying the level of tolerable risk.

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[3] This section has been moved from 5.2 "Risk management options assessment" to 5.1 "Initial risk management activities" to ensure a better match with the structure of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety (Paper No 65, Rome 1997).

[4] A definition of tolerable level risk will be prepared by USA, ICMSF and France in order to make a link with appropriate level of protection.

[5] This new section 5.1.8. corresponds to section 5.2.2. of the previous version. This change results from the ICMSF's suggestion that a section on setting of tolerable risk levels be inserted in part 5.1, incorporating the sixth and eighth paragraphs of section 5.2.4.1. "Food safety objectives" from the previous version.

The level of tolerable risk will define the appropriate control measures.

Decisions on tolerable levels of risk should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. Consideration of other factors (e.g. economic costs, benefits, technical feasibility, and public risk reduction preferences [and public values]) may be appropriate in some risk management contexts, particularly in the determination of measures to be taken. These considerations should not be arbitrary and should be made explicit.

Determining the tolerable level of risk should be an on-going exercise, and may involve considerations of the following:

- The risk assessment including the magnitude, severity and reversibility of the health effects and its attendant uncertainties, and the possibility of susceptible subpopulations.
- The magnitude of nutritional benefits of a product.
- Risks, including chemical, physical and biological risks that may arise from microbiological risk management interventions.
- Technical feasibility of prevention and control options.
- Cost of prevention and control versus effectiveness of risk reduction.
- Public risk reduction preferences, [public values].
- Distribution of risks and benefits
- [Others factors when appropriate].

5.19 Regional considerations[6]

In the interests of safeguarding human health and minimising the incidence of foodborne diseases, the existence of regional differences in the prevalence of various pathogens in the food chain *should* be recognized and taken into account in the risk management process. Principles which apply in this regard include the following.

- Risk management should be based on microbiological prevalence data, when available, from the whole food chain and, if appropriate, disease incidence data.
- Risk management should take into account the existence of regional differences in the prevalence of foodborne pathogens in the food chain.
- Ranking of hazards can be carried out at international, regional or national level.

[6] According to the discussions of the working group, these section has been removed from 5.2 to 5.1.

5.2 RISK MANAGEMENT OPTIONS ASSESSMENT

5.2.1 Identification of available options

Microbiological risk management options assessment should be aimed at setting a range of protective goals in terms of risk reduction and risk prevention.

The primary objective of microbiological risk management options assessment is an optimization of the interventions necessary to prevent and to control microbiological risks. It is aimed at selecting the option or options that achieve the chosen level of public health protection for the microbiological hazard in the commodity of concern in as cost effective manner as possible within the technical feasibility of the industry.

Available options may be identified at national, regional or international level in the context of international trade agreement provisions.

There might be many different options for reducing microbiological risks, such as:

- avoiding foods with a substantiated history of contamination or toxicity;
- preventing contamination and/or introduction of pathogens at any stage in the food chain including reducing the level of specific pathogens in primary production;
- preventing growth of pathogens by the combined action of extrinsic factors (e.g. chilling or freezing) and/or intrinsic factors (e.g. adjusting pH, Aw; adding preservatives; employing microbiological competition);
- destroying pathogens (e.g. cooking, irradiation);
- establishing regulatory requirements and/or creating incentives for changes in attitudes that will contribute to risk reduction;
- establishing microbiological standards or other criteria and enforcing compliance;
- establishing microbiological food safety objectives;
- educating / informing the population at large or affected sub-groups about the steps they can take to reduce risks.

Usually, a combination of options will be more effective in reducing risks.

In the case where scientific knowledge of the risk is insufficient, it may be appropriate for risk managers to apply a precautionary approach/ principle, through interim measures.

5.2.1.1 Microbiological Food Safety Objectives[7]

[A Microbiological Food Safety Objective (MFSO) can be useful tool in microbiological risk management.

[7] Examples of MFSO could be developped later on.

A MSFO is a statement [based on a risk analysis] which expresses the level of a hazard in a food that is tolerable in relation to an appropriate level of protection.

MSFOs should contain three components: the food of concern, the hazard of concern and an expression of the appropriate level of protection for the hazard. MSFOs should, preferably, be quantitative in nature (maximum tolerable frequency and/or frequency). The appropriate level of protection is a reflection of a particular country's public health goals relative to the application of the sanitary measures.

MFSOs should be technically achievable and practicable.

MFSOs can serve a number of functions, including:

- Provide a reference for the overall design of good hygienic practices and HACCP-based food control systems.
- Provide a target for the validation of sanitary measures for segments of food production systems, or for food production systems in their entirety.
- Form a basis for derivation of performance and hazard criteria in a food production system.

Primary users of MFSOs are governments and the food industry.

MFSOs can be used:

- By governments to communicate the expected level of food safety to the food industry. MFSOs to do not prescribe how the expected level of food safety can be achieved, leaving it to the food industry to select the appropriate technology including the establishment of process and performance criteria.
- By the food industry to show that their products meet the established tolerable level of risk for the specified hazard.
- By governments to communicate the expected level of food safety to consumers.

At the international level, MFSOs can be used in the determination of equivalence by showing that different sets of control measures meet the same level of protection.

Because significant differences in the occurrence of food borne pathogens can be found between different countries or regions, MFSOs in general and more specially sampling plans, criteria, etc., should not be universally common but should take into account national and regional situations].

5.2.1.2 Precautionary principle

[Precautionary Principle - A decision-making approach which may be applicable when there is a suspicion of adverse effects but where there is no evidence as to the existence or extent of risks to human health, leading to protective measures without having to wait until the reality and seriousness of risks to human health become apparent.]

This item is under consideration within the discussions of the CCGP (15th Session April 2000). At present, no consensus was reached on this issue and the subject is out for comment through a circular letter (cf.background and annex I).

5.2.2 Selection of preferred microbiological risk management options

Once identified, potential options should be assessed by risk managers and by stakeholders.

In this assessment process, the protection of human health, based on scientific knowledge of the microbiological hazards and the scientific understanding of the primary production and processing technology, should be the primary considerations.

The relevant production and processing methods, the inspection, sampling and analysis methods, the difficulties [or operations] involved in control, inspection and compliance with requirements [and approval procedures] should be taken into account.[8]

However, other important elements should be considered, as appropriate. These elements could include technical and economic feasibility, cost-effectiveness of alternative approaches to limiting risk, and the tolerable level of risk, taking into account preferences expressed by stakeholders .

The assessment should also consider whether an option may cause adverse consequences such as:

- the potential for an option to increase one type of risk (e.g. chemical risk) while reducing the microbiological risk of concern; or
- the potential for an option to impact the nutritional status of the population;
- the potential for an option to disregard a population group's preferences.

5.2.3 Final management decision

Which option or combination of options is optimal depends on each particular situation.

From a general point of view and in order to be meaningful and practicable, the final management decision should:

- give priority to preventing risks, not just controlling them;
- address the whole farm to table continuum;
- offer a choice, as far as possible, between risk control options which achieve an appropriate level of public health protection to be achieved ;
- be based on the best available scientific, technical and economic information;
- be feasible, with benefits reasonably related to costs;
- be enforceable within the country's legal and regulatory structure;
- take account of the level of risk deemed appropriate by risk managers, considering all stakeholder preferences relevant for the health protection of consumers.

[8] comes from principle 9 (previous version)

6. GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

The implementation of microbiological risk management decisions, can be by both governmental officials and by representatives of the food industry. Implementation will take different forms depending upon the options that have been decided.

In some situations, it may be preferable to utilize historical regulatory approaches. These approaches may be most successful in ensuring that fundamental good manufacturing practices are maintained. The most traditional tools for implementing microbiological risk management decision have been regulatory command and control or periodic inspection/end product testing that is enforced through penalties for non-compliance. While this system has resulted in significant reduction to the contamination levels in foods, it presents certain limitations. These systems place the burden of compliance with the regulatory authority rather than with the food manufacturer and the consumer. Where a substantial pathogen level reduction has already been achieved, the rigidity of existing systems cannot provide the flexibility for tailoring remedies to individual situations in a cost-effective manner.

In most cases, however, an integrated systems approach to ensuring the safety of foods is preferable. Risk management decisions should address the entire farm to table continuum. HACCP, in combination with prerequisite programes, is one such system. Such an approach places the responsibility for ensuring safe foods with the producer, the manufacturer, the distributor and the retailer[1], effectively using regulatory resources to provide the necessary oversight.

[MFSO's may function as important management tools in the implementation of risk management decisions. MFSOs communicate to food producers the level of safety that should be achieved and facilitates the optimal use of limited regulatory resources.]

In the field of food microbiology, microbiological testing against microbiological criteria (whether included in regulations as standards or only advisory) has been widely used as a management tool to determine the acceptability of products in trade. Microbiological criteria retain their value as a possible implementation tool of microbiological risk management decisions. However, end product testing is limited in its ability to assess the safety of food and cannot adequately assure the absence of pathogens. The inherent low prevalence of most foodborne pathogens makes it statistically impossible for end product testing to ensure the safety of foods. Microbiological testing is more properly utilized to verify the proper implementation of HACCP, to validate control measures and to assess problems either where HACCP has not been employed or where access to HACCP verification information is limited or unavailable. When microbiological criteria are used, reference should be made to the Codex document *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

7. MONITORING AND REVIEW

Risk managers should periodically determine that risk management measures have been implemented. Moreover, they should periodically assess the effectiveness of measures taken.

Risk management decisions should be reviewed as new information becomes available. Such data include new information on the virulence of the organism, the prevalence and level of the organism in foods, the extent of sensitive populations, changes in dietary intake pattern, changes in food processing patterns, as well as data from epidemiological studies and surveillance and monitoring programme in relation with foodborne diseases.

With respect to governments, tools used to evaluate the risk management process may include reviewing the effectiveness of the regulatory control programmes, and reviewing information relating to the foodborne pathogen(s) targeted for control such as disease surveillance or research, re-analysis of costs and benefits and discussion with stakeholders.

For appropriate implementation of this stage of the microbiological risk management process, a plan should specify when evaluation should be conducted, who will conduct it and what will be evaluated.

Evaluation might first focus more on effectiveness and progress implementing the microbiological risk reduction. Later, evaluations may focus on the success of the microbiological risk management actions in reducing risk.

With respect to industry, tools used to evaluate the risk management process may include reviewing the effectiveness of HACCP and its pre-requisite programs, reviewing product analytical testing results, and reviewing the incidence and nature of product recalls and consumer complaints.

These tools may also be used, if necessary, by governments when evaluating the risk management process.

Results of monitoring and/or new information may warrant repeating part of the risk management and/or the risk assessment activities to ensure that the on-going risk management programme remains effective.

ANNEX I

The Application Of Precaution In Risk Management : Precaution Principle Or Approach

Two alternatives propositions drawn up at the 15th session of the CCGP (ALINORM 01/33-Appendix III, par.34 and 35)

"The two following paragraphs are alternative proposals :

34. [Where relevant scientific evidence is insufficient, precaution can be exercised as an interim measure to protect the health of consumers. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe].

34. [When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food[a], and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria[b]:]

35 [In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process :

- Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.
- The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data.
- There should be a transparent explanation of the need for the measures and the procedures followed to establish them.
- The decisions taken are consistent with those taken in similar circumstances and are the least trade-restrictive necessary to achieve protection of the health of consumers.
- The decisions are provisional and are subject to an on-going, transparent review process involving interested stakeholders.
- Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information.

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[a] It is recognised that hazard identification is a crucial step in this process.
[b] Some members refer to this concept as the "precautionary principle".

- Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.]"