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 AT STEP 3*

(Document prepared by France)

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 and the 22nd Session of the Codex Alimentarius Commission approved it as new work (ALINORM 97/37, para. 130 and Appendix IV).

The Committee, at its 30th Session, considered a paper on *Recommendations for the Management of Microbiological Hazards in Foods in International Trade (CX/FH 97/10)* which included a step-wise set of recommendations for the management of microbiological hazards in food in international trade. The Committee 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 ICMSF. Based on the efforts of a drafting group chaired by France, a revised paper was prepared that incorporated, among other things, the concept of Food Safety Objectives.

The 31st Session of CCFH considered the revised paper and accepted a proposal that its title be changed to *Principles and Guidelines for the Microbiological Risk Management.* The Committee generally agreed that - the concepts presented as recommended principles in the Appendix to document *on The Implications of Regional Differences in the Prevalence of Foodborne Pathogens in the Management of Microbiological Hazards for Foods In International Trade (CX/FH 98/13)* - should be considered for incorporation into this document. The Committee further agreed that the Delegation of France, with the assistance of a drafting group would redraft the paper for consideration by the 32nd Session of CCFH.

The revised document presented below, takes into account the instructions of the 31st Session of the Committee. The paper has been reorganized to more clearly present the steps in microbiological risk management. The paper more clearly articulates a set of principles for microbiological risk management, incorporates a new section on regional considerations, a new definitions section and a draft section on the precautionary principle. The section on Food Safety Objectives is unchanged and has been placed in brackets, recognizing that work is progressing on this concept in other Codex Committees.

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* **Secretriat's note:** *Due to time constraints written comments are not requested on the document.*

The Committee is invited to consider the revised document with a view towards advancing it in the Codex Step Procedure (see Appendix).

Appendix

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

TABLE OF CONTENT

INTRODUCTION

Risks from microbiological hazards are of immediate and serious concern to human health.. Microbiological Risk Analysis is a process consisting of three components: Risk Assessment, Risk Management and Risk Communication, which has the overall objective to ensure public health protection. This document deals with Risk Management, which is a key element in assuring the control of microbiological hazards in food.

The following principles and guidelines present the different elements of microbiological risk management, indicating what should be considered at each step of the process. These guidelines and principles are intended to be used by public authorities. However, they are useful for risk managers in industry, 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.

[Food Safety Objective - A statement expressing the level of hazard in a food that is tolerable in relation to an appropriate level of protection.]

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

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[1].

Risk Assessment Policy -- Guidelines for value judgement and policy choices which may need to be applied at specific decision points in the risk assessment process[2].

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[3] - The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, 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.

Risk Management[3] - 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.

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: Risk management processes should be structured.
- PRINCIPLE 4: Processes and decisions should be transparent and fully documented;
- PRINCIPLE 5: 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.

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[1] Codex Alimentarius Commission Procedural manual, 10th edition, pages 44-45
[2] To be developed by the Codex Committee on General Principles
[3] ALINORM 99/37, para. 70 and Appendix IV.

- PRINCIPLE 6: Risk managers should take into account the uncertainty of the risk estimate when making risk management decisions.
- PRINCIPLE 7: In 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.
- PRINCIPLE 8: 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 9: Risk management decisions should address the whole farm to table continuum, including imported foods.
- PRINCIPLE 10: Risk managers should ensure that any control measures that are to be implemented are optimal regarding their feasibility, efficiency and are proportionate.
- PRINCIPLE 11: Risk management should be a continuing process that takes into account all newly generated data. Such data include new information on the virulence of the organism, the incidence 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 epidemiological data and foodborn disease surveillance programs.
- PRINCIPLE 12: The efficiency of risk management measures has to be periodically assessed with regards to the risk management goals. As appropriate these measures have to be reviewed.

4. INVOLVEMENT OF STAKEHOLDERS

The involvement of stakeholders[4] in the risk management process is essential in order to ensure a transparent and effective process. Stakeholders involvement provides opportunities for interactive exchange of information and opinion about risk. It may also help to bridge gaps in understanding, to contribute to the sharing of values and perceptions, and to facilitate the 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 stakeholders 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:

[4] *stakeholders means interested parties*

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.

5.1.2. Identification a problem

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

Methods and indicators to identify problems may include data on the presence, prevalence and concentration of hazards in the food chain and in the environment, disease surveillance information, epidemiological studies, clinical studies, laboratory studies, production practices including process innovation, lack of compliance with standards, expert and public opinion.

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 assessment management process as outlined in this document should normally not be undertaken for food hygiene situations that can be routinely handled or expeditiously managed by applying the "Recommended International Code of Practice: General Principles of Food Hygiene" or specific commodity codes of hygienic practice".

5.1.3. Risk profile

Elaboration of a risk profile, that is describing a microbiological food safety problem and its context, is essential for effective risk management. Elaboration of a risk profile is a situation analysis used to determine the size and nature of the problem and what action(s) may be necessary, including whether a risk assessment should be carried out. A typical microbiological risk profile might include a brief description of the situation, the products or commodities involved, what is expected to be at risk (e.g. human health, economic concerns), the potential consequences of actions taken, the consumer perception of the risks, and the distribution of risks and benefits.

Describing a microbiological problem can involve the following:

- delineating which microbiological hazard(s) are causing the problem and the difficulty in controlling them;
- determining 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);
- considering available prevalence and concentration data from the whole food chain;
- considering disease incidence data and identifying the types and severity of the adverse effects;
- determining which populations may be affected (for example, at risk groups such as the elderly, infants and children, the immune-compromised, or those whose exposure to the microbial hazard may be increased due to dietary intake; socioeconomic status, or other characteristics);
- identifying how stakeholders perceive the problem.

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. However, it has to be kept in mind that 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 also involve public values; they may be directed by statute, policy or regulatory considerations, or economic constraints. One management goal can be to establish Food Safety Objectives (FSOs) 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 this 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.

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 that the risk characterization will incorporate and provide 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 reflect the previously articulated risk management goals to 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 at the point of consumption 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 in the Codex *Principles and Guidelines for the Conduct of a Microbiological Risk Assessment* (CAC/GL-30 (1999)).

5.2. RISK MANAGEMENT OPTIONS ASSESMENT

5.2.1. Consideration of the process and the results of the microbiological risk assessment

For the best use of a microbiological risk assessment product, 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 should 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 characterization should 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.

5.2.2. Identifying the level of tolerable risk

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

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

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;
- substitution 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].

5.2.3. Regional considerations

For the sake of human health protection and to minimize the incidence of food-borne diseases, the existence of regional differences in the prevalence of various food-borne pathogens in the food chain could be recognized and could be 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 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 food-borne pathogens in the food chain;
- ranking of hazards can be carried out at the national, regional or international level.

5.2.4. Identification of available options

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

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.

There might be many different approaches to measures 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;
- 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.

Different tools might be available to conduct these approaches, such as:

- establishing microbiological standards or other criteria and enforcing compliance;
- establishing food safety objectives;
- the precautionary principal.

5.2.4.1. Food Safety Objectives

[A Food safety Objective (FSO) can be a useful tool in the microbiological risk management.

The function of a FSO is to express the level of a hazard in a food that is tolerable in relation to an appropriate level of consumer protection. This is reflected in the following working definition:

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

When justified by the risk assessment, the FSO should express the level of the hazard as its maximum tolerable frequency and/or concentration.

The FSO must be technically achievable and practicable.

Decisions on acceptable 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 societal preferences) 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.

FSOs should contain three components: type of food, hazard of concern and the appropriate level of consumer protection[5]. The appropriate level of consumer protection is a reflection of a particular country's public health goals relative to the application of sanitary measures.

For foods in international commerce the appropriate level of protection represents a consensus of what participating countries or governments are willing to tolerate in relation to their food supplies. Once a consensus has been reached on what is considered appropriate, it should be incorporated into an FSO for communication to all affected parties. Industry and regulatory authorities should then adjust their control and inspection systems to meet the FSO.

FSOs are food safety management tools, which can provide a number of functions. A few examples are:

- FSOs provide a reference for the overall design of good hygienic practices and HACCP based food control systems;
- FSOs provide a target for the validation of sanitary measures for segments of food production systems, or for food production systems in their entirety;

[5] *The appropriate level of protection is a reflection of a particular country's public health goals relative to application of sanitary measures. Decisions on appropriate levels of risk should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. The statement of appropriate level of sanitary protection in the WTO SPS Agreement is "The level of protection deemed appropriate by the Member establishing a sanitary measure to protect human health. NOTE - Many Members otherwise refer to this concept as the acceptable level of risk."*

- FSOs may form the basis for derivation of performance and hazard criteria for steps in a food production system.

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

5.2.4.2. Precautionary principle[6]

[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.]

5.2.5. Selection of preferred microbiological risk management option

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 consideration.

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

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.

5.2.6. 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:

- address the whole farm to table continuum;
- be based on the best available scientific, technical and economic information;
- be feasible, with benefits reasonably related to costs;
- give priority to preventing risks, not just controlling them;
- be enforceable within the country's legal and regulatory structure.
- account for the level of risk, deemed appropriate by risk managers, considering all stakeholders preferences.

6. GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

The implementation of microbiological risk management decisions will take different forms depending upon the options that have been decided.

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[6] To be developed

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 consistent amount of 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. ACCP, in combination with necessary prerequisites is one such system. Such an approach places the responsibility for ensuring safe foods with the manufacturer, effectively using regulatory resources to provide the necessary oversight.

[FSOs may function as important management tools in the implementation of risk management decisions. FSOs communicate to food producers the level of safety that should be achieved and facilitate 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 can not adequately assure the absence of pathogens. The inherent low prevalence of most food borne pathogens makes it statistically impossible for end product testing to ensure the safety of foods. Microbiological testing is most properly utilized to verify the proper implementation of HACCP or to assess problems either where HACCP has not been employed or where access to HACCP verification information is limited or unavailable. When consideration is being given to the utilization of microbiological criteria, 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 evaluate the effectiveness of measures taken.

Tools used to evaluate the risk management process may include reviewing the effectiveness of the regulatory control programs, and reviewing information relating to the food borne 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.

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 program remains effective.