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 OF THE PROCEDURE)

Prepared by France with assistance of Argentina, Australia, Canada, Denmark, Germany, Netherlands, New Zealand, Norway, Sweden, United Kingdom, United States, Consumers International and ICMSF.

Governments and interested international organizations are invited to submit comments or information on the attached Proposed 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, Twelth Edition*, pages 19-20) **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 15 December 2002.**

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.

The 33rd Session of the Committee agreed to return the document to Step 3. It was further agreed that the Delegation of France, assisted by its drafting partners, would revise the document, taking into account the comments of this Session, the report of the WHO Kiel Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards and any comments that are received in response to the CL on FSOs. The Committee decided to draw the attention of CCGP to the importance of reaching a resolution on the issue of precaution in order for this document to progress.

The 34th Session agreed to revise the document taking into account the comments of this Session, the draft report of the WHO Kiel Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards and any comments that are received in response to the CL 2001/32-FH on the development of the sections 6 and 7.

REVISED DOCUMENT

This document has been modified according to the discussions of the last meeting of the working group in Paris on 27, 28 and 29 may 2002.

In particular, the following points were developed :

- the separation in each section between the application of microbiological risk management with respect to Codex and application of microbiological risk management with respect to countries,
- the relationship between the ALOP, an FSO and performance criteria,
- the implementation of microbiological risk management decisions and the monitoring and review of these decisions with the complete revision of sections 6 and 7.

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[1].

[1] **Secretariat note:** Some modifications made by the *ad hoc* Drafting Group did not take into account decisions of the 34th Session of the Committee, therefore Secretariat amended the document accordingly.

Appendix

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT – At Step 3 of the Procedure

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INTRODUCTION

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

The rise in globalization of the foodmarket 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 these risks 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, organizations 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, the Food and Agriculture Organisation* and *the Codex Alimentarius (e.g. FAO/WHO Expert Consultation on Risk Management and Food Safety-Paper N°65, Rome 1997, WHO Expert Consultation, The Interaction between Assessors and Managers of Microbiological Hazards in Food, Kiel, Germany, March 2000, The Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts, draft report Kiel, Germany, March 2002).* Additionally, particular reference should be paid to the Codex working principles for risk analysis for application within the framework of Codex Alimentarius (under development in the Codex Committee on General Principles).

The following principles and guidelines present the different components of microbiological risk management, indicating what should be considered and would be involved at each step of the process.

1. SCOPE

These principles and guidelines provide a framework for the management of risks arising from the occurrence of microbiological hazards in foods. They provide information both on the risk management process itself and on the implementation of risk management options, including decisions related to the need to conduct risk assessments. Nevertheless, once the purpose and scope of a risk assessment have been defined in a risk profile document, the assessment should follow the framework identified by the Codex *Principles and Guidelines for the Conduct of a Microbiological Risk Assessment* (CAC/GL-30 (1999)).

These principles and guidelines for risk management are intended for application in the framework of *Codex Alimentarius* and also are intended to provide advice to public authorities including governments.Additionally, they are useful information for risk managers in industry and for other interested parties in order to apply a common framework for microbiological risk management.

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

2. DEFINITIONS

The following definitions are provided here to facilitate the understanding of certain words or phrases used in this document. Many of the definitions appear in the Procedural Manual of the Codex Alimentarius Commission, Twelth Edition, Rome 2001).

Appropriate Level of Protection (ALOP) : Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory[2]

[2] definition taken from WTO/SPS agreement

For the purpose of these guidelines an ALOP refers to a level of protection of human health established for a foodborne microbiological hazard.

Food Safety Objective - The maximum frequency and/or concentration of a [microbiological] hazard in a food at the time of consumption that provides the appropriate level of health protection [(ALOP)].

Example of FSO: 100 *Listeria monocytogenes* per gram of ready-to-eat food.

Hazard - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect[3].

A microbiological hazard is a hazard arising from bacteria, viruses, yeasts, moulds and algae, parasitic protozoa and helminths, and their toxins or metabolites**.**

Microbiological criteria : A microbiological criteria for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.[4]

Stakeholder : Any individual, group or organisation that may affect, be affected by, or perceive itself to be affected by the risk or risk management activities.

Performance criteria : The required microbiological outcome of one or more control measures at a step or combination of steps that contribute to assuring the safety of a food.

Process criteria : The process control parameters (e.g. time, temperature, dose…) at a specified step that can be applied to achieve a performance criteria.

Risk - A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food[2].

A microbiological risk is a risk arising from the presence in food of bacteria, viruses, yeasts, moulds and algae, parasitic protozoa and helminths, and their toxins or metabolites

Risk Analysis - A process consisting of three components: risk assessment, risk management and risk communication[2] .

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 – Elaboration of guidelines for the choice of options and associated judgements as well as for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained[5].

Risk Characterization - 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[2].

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[2].

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[3] these definitions are taken from the Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition.
[4] definition taken from Codex (CAC/GL 21-1997 Recommended International Code of Practice-General Principles of Food Hygiene)
[5] definition from CCGP : *CX/GP 02/3*

Risk Management - The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment when available 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[2]. This process can be managed at the national, regional or international level.

[Risk Management Policy – Guidance provided for value judgment or policy choices, and provision for apportionment of adequate resources and peer review.[6]]

Risk manager : The representative of government at a national level or regional level or representative of international organization at the international level who has the responsibility of risk management.

Risk Profile - A description of a food safety problem and its context so as to guide further risk management action.

[Product tracing/traceability: A microbiological risk management tool that provides the ability to identify by means of paper or electronic records, a food product and its producer, from where and when it came and to where and when it was sent[7].]

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 between stakeholders during various aspects of the process, as appropriate.
- PRINCIPLE 3: Processes and decisions should be transparent and fully documented.
- PRINCIPLE 4 : The establishment of risk assessment policy is a responsibility of the risk managers. The objective of risk assessment should be clearly defined before the risk assessment begins.
- PRINCIPLE 5: The scientific integrity of the risk assessment process should maintain the functional separation of risk management and risk assessment, while ensuring transparent and appropriate interaction between them.
- PRINCIPLE 6: Risk managers should take into account the uncertainty of the risk estimate when making risk management decisions.
- [PRINCIPLE 7: In the case where scientific knowledge of the risk is insufficient, it may be appropriate for risk managers to apply a precautionary approach, through interim measures].
- 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 take into account the whole food chain from primary production to consumption including imported foods, and should be implemented in the context of appropriate food safety infrastructures (e.g. regulatory enforcement, food product tracing/traceability systems).
- PRINCIPLE 10: Risk managers should ensure that any control measures that are to be implemented should be feasible, effective and proportionate to the risks identified.

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[6] wording *from the WHO Expert Consultation on "The Interaction between Assessors and Managers of Microbiological Hazards in Food (Section 5.4, 2nd paragraph, p. 9).*

[7] this definition should follow the work undertaken by the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and other Committees in this area.

- PRINCIPLE 11: Risk management decisions should always be open to review. Risk management decisions should be open to review when new information becomes available that substantively alters the conclusions of risk assessment or its associated degree of uncertainty, or as new risk management options become available.
- PRINCIPLE 12: The effectiveness of risk management measures should be periodically assessed with regard to the risk management goals and the measures should be revised if appropriate.
- PRINCIPLE 13: Risk management goals should be periodically assessed in order to encourage continuous improvements relating to public health risk.

4. INVOLVEMENT OF STAKEHOLDERS

Within Codex, stakeholder involvement is provided through member countries and through input from international intergovernmental organizations and international non-governmental organizations (INGOs). This input provides information that may subsequently be communicated to member countries for consideration by stakeholders at the national level.

Within the national context, stakeholders include, but are not be limited to, governmental bodies, consumers and their organizations, representatives of the food industry and their organizations, primary producers and their organizations, trade organizations, and representatives of professional, educational and research organizations.

The involvement of stakeholders 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.

When involving stakeholders, efforts should be made to ensure that there is a balanced representation of different interests. Furthermore the interest represented should be clearly and transparently stated.

Involvement of stakeholders can be implemented in many ways, ranging from public meetings to opportunities to comment on public documents and using appropriate forms of mass media.

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

Stakeholders should be involved in various aspects of risk management, as appropriate, for example :

- [Development of the risk profile, since it must accurately reflect the concerns and perception of the various stakeholders;
- Identification of the purpose and objectives of the risk assessment;
- Establishment of the risk assessment policy, since it involves values and policy judgements;
- Identification of risk management options;
- Identification of the ALOP and establishing FSOs;
- Selection of the preferred risk management options;
- Review of the risk management and the underlying public health goals.]

The risk management decisions and the procedure used to reach the decisions should be fully and systematically documented and available to all stakeholders upon request, in order to ensure transparency.

5. GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

The general steps in the microbiological risk management decision making and implementation process are the following, recognizing that not all steps will always be necessary, and that the order of steps may vary on a case-by-case basis.

- Determine that control of a specific microbial pathogen in a specific commodity (commodities) is required;
- Conduct a risk assessment to understand the relationships between the pathogen and public health and, when possible, evaluate the impact of potential mitigation or intervention strategies;
- Establish the ALOP for the pathogen/commodity combination;
- Establish a FSO for the pathogen/commodity combination;
- Establish the performance criterion for the pathogen/commodity combination;
- As appropriate, decide upon and/or provide guidance on appropriate validated food safety control measures that may be used to control the pathogen in the foods of concern;
- Determine the need and nature of additional risk management programmes including those relating to supplemental guidance information on hazard control, training, education, outreach and research;
- Implement the risk management decision(s);
- Carry out periodic verification that the risk management decision(s) is working properly.

Annex 2 provides a diagram explaining differences and possible relationships of the main concepts.

Risk communication has an important role in engendering trust in risk management. It should be planned and started as early as possible in the risk management process and evaluated on a regular basis. It is important to identify which parties need to be involved in communication, and how and when opportunities for communication will be provided. Effective communication between all parties involved in risk analysis is essential and the information communicated should be appropriate to the situation and intended audience.

5.1 PRELIMINARY RISK MANAGEMENT ACTIVITIES

5.1.1 Identification of risk managers

At the outset of a microbiological risk management activity, the risk managers should be identified and when appropriate their roles clearly distinguished from the roles of risk assessors.

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 the context of Codex, microbiological risk management will normally be the responsibility of the Codex Committee on Food Hygiene while risk assessment will normally be the responsibility of the FAO/WHO Joint Expert Group on Microbiological Risk Assessment.

With respect to countries, competent authorities play a pivotal role in microbiological risk management and risk assessment. The industry which has the responsibility for producing safe products may also play a significant role in this area.

While it is a desirable goal that the persons and bodies involved in risk assessment and risk management be different individuals or organizations, it is recognized that in many countries this separation is not possible due to limited resources and in that case, risk assessors and risk managers may have dual roles.

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 for instance to take account of any new developments that may have arisen during the risk assessment and risk management activities.

It is always desirable to seek stakeholders comments on risk assessment and risk management activities as a means to avoid bias and enhance transparency, particularly when a clear separation of these functions is not feasible.

5.1.2 Identification of a microbiological food safety issue

A food safety issue is a situation where a public health hazard associated with a food (e.g., a pathogenic microorganism) creates a risk that needs to be managed. A specific food safety problem should be clearly identified and communicated. A food safety problem may already be well recognized and or may be a new or latent problem.

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

Food safety issue 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.

A key step in microbiological risk management is determining the available resources (human, financial, time) for addressing the food safety issue[8].

5.1.3 Microbiological Risk Management Policy

Establishing microbiological risk management policy is the responsibility of risk managers. Microbiological risk management policy serves to protect the integrity of the risk management process. Additionally, as with microbiological risk assessment policy, the establishment of a microbiological risk management policy helps to ensure the transparency and unbiasedness of the risk management process.

Implementation of risk management policy may occur across the continuum of risk management activities. Some elements of risk management policy may be broad and overarching and occur prior to the initiation of any actual risk management activities (e.g., establishing priorities for risks to be managed) while other elements may occur during a specific risk management process, including after the establishment of risk assessment policy and after initiating interaction with risk assessors and/or the selection of risk management options (e.g., establishing guidelines for the selections of options to manage the risks).

Microbiological risk management policy can include establishing guidelines for the following:

- Priorities for which microbiological risks are to be managed.
- Interaction between risk managers and risk assessors.
- The selection of options to manage the microbiological risk, including control measures and risk communication programmes.
- Determining which factors to use in the evaluation and selection of options (e.g., economic feasibility, technical feasibility).
- The allocation of resources to undertake microbiological risk management activities.
- The peer review process.

[8] proposition of the USA. The presidency of the working group suggests to include this important comment in Chapter 3) General principles.

- Risk communication.

All these elements during the process can lead to a change of the Risk Management policy.

5.1.4 Microbiological risk profile

Elaboration of a microbiological risk profile is essential for effective microbiological risk management. The risk profile should place the food safety issue within a particular food safety context and provide as much information as possible to guide further action.

A microbiological risk profile provides an initial evaluation of the food safety issue in relation to the scope of the public health concerns, the extent of pertinent scientific information and available control measures. This can include an initial evaluation of the advisability and feasibility of conducting risk assessment.

Preparing the profile is a responsibility of the risk manager (although it may be commissioned out). In Codex, the draft risk profile will generally be prepared by a country or group of countries, after which it will be discussed in the Committee.

The person/group preparing the profile needs to determine at the outset what information is needed, how they will obtain it, and from where/whom.

Typically the risk profile should be a short document completed in a timely manner, depending on the time available to make a decision and the nature of the issue. Risk profile is not intended to substitute to hazard identification.

Annex 1 provides information about appropriate risk profile elements.

5.1.5 Defining goals

The goals for a microbiological risk management activity should be identified before a risk assessment begins 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.

For Codex, CCFH defines the goals. The goals for CCFH include strategic management of the hazard(s) in the commodity(s) of concern and the development of specific risk management guidance.

For countries, the goal is in particular to develop preferred risk management measures to control a specific hazard(s) in a specific commodity(s). Goals may be directed by statute, policy or regulatory considerations. Goals may also be influenced by economic factors and the consumer's perception of the microbiological risk.

At the same time, risk management decisions should, to the extent possible, ensure fair practices in the food trade**.**

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

5.1.6 Microbiological risk assessment

5.1.6.1 Microbiological risk assessment policy

Microbiological risk assessment policy setting is a risk 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 stakeholders.

In this respect there should be a clear determination of risk assessment policy before risk assessment commences. Risk assessors must document the impact of these policies on the assessment.

Typically, a microbiological risk assessment policy should address the issues of transparency -and "unbiasedness" in the risk assessment process as well as the issues of clarity, consistency and reasonableness in the risk assessment products.

Risk assessment policy should include the determination of when a quantitative risk assessment is required. Microbiological risk management necessarily requires an evaluation of the risk posed by a hazard. However this does not always require that a quantitative risk assessment be carried out.

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, for value judgements or policy choices, and make provisions for apportionment of adequate resources, and for peer review.

5.1.6.2 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 risk managers 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 should focus on ensuring that risk assessors and stakeholders fully understand 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 proposal regarding the level of a pathogen in a ready-to-eat product to attain an appropriate level of protection with a high degree of confidence.

Interaction between assessors and managers should continue during all the process of risk management. This interaction should allow in particular the determination of timeframe within which the risk assessment is to be conducted.

5.1.7 Consideration of the process and the results of the microbiological risk assessment

For the best use of a microbiological risk assessment, managers should be fully informed of the strengths and limitations of the risk assessment. Communication of the following points with regard to the microbiological risk assessment is important to ensure that they are appropriately carried out by risk assessors:

- The relevant assumptions and their quantitative impact on the outcomes of the risk assessment should be fully acknowledged to facilitate stakeholder understanding.
- All risk characterisations should explicitly address sources of variability and sources of uncertainties.
- Risk characterisations may be a range of risk estimates based on different data, assumptions, models, and disease manifestations rather than the presentation of a single risk estimate. Narratives should accompany risk characterisations and fully communicated and/or explained.
- When possible the risk assessment should be subject to a peer review. Any possible differences in the conclusions should be solved by the risk managers, with input from the risk assessors and stakeholders as appropriate.
- Risk characterisation may address both the present situation and, as appropriate, various options for managing the risks, including options relating to risk reduction and substitution risks.

5.1.8 Regional considerations

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 recognised 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 and prevalence data.
- Risk management should take into account the existence of regional differences such as the prevalence of foodborne pathogens in the food chain.
- Ranking of hazards can be carried out at an international, regional or national level.

5.2 ASSESSMENTOF RISK MANAGEMENT OPTIONS

5.2.1 Determining the appropriate level of protection (ALOP)

For countries that are signatory to the international trade agreements of the World Trade Organisation, foods in international trade are subject to the provisions of these agreements. For food safety, the applicable agreement is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). A key provision of the SPS Agreement is the Appropriate Level of Protection (ALOP), the level of protection deemed appropriate by the country establishing a sanitary measure(s) to protect human health within its territory.

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

An Appropriate Level of Protection (ALOP) can be implicit or explicit. An implicit ALOP is most often stated in terms of broad public health goals or in relation to legal requirements ("reasonable certainty of no harm"). However, effective implementation of the ALOP often requires a more explicit articulation of public health expectations. An explicit description of an ALOP may be in terms of a probability of an adverse public health consequence or an incidence of disease (e.g., the number of cases per 100,000 population per year associated with a hazard in food). [Since in some cases it will be impossible to give exact estimates of the ALOP, an ALOP could also be expressed as an aim of reducing the number of cases in a population associated with a hazard in food].

The ALOP/ALR applies equally to both domestic and imported food. The ALOP/ALR should be [scientifically justifiable and] clearly conveyed to the exporting country.

Determining the Appropriate Level of Protection (ALOP) for a particular hazard(s) in a specific commodity(ies) is the responsibility of countries. Codex can help the countries by providing information to governments on specific sanitary measures and associated levels of risk thereby facilitating national decisions relating to the ALOP.

The following information is intended as guidance to countries on establishing an ALOP.

Decisions on ALOP should be determined primarily on the basis of the risk to human health for the food borne pathogens, including the magnitude, frequency, severity and reversibility of the health effects and its attendant uncertainties, for the general population and any susceptible subpopulations, keeping in mind that risk assessment need not always require a quantitative risk assessment. Consideration of other factors may be involved in determination of ALOP including the following examples :

- Technical feasibility of prevention and control options.
- Risks, including chemical, physical and biological risks that may arise from microbiological risk management interventions.
- The magnitude of nutritional benefits of a product and the availability of dietary substitutes.
- Cost of prevention and control versus effectiveness of risk reduction.
- Public risk reduction preferences, public values.

- Distribution of risks and benefits .

The ALOP should be periodically reviewed with respect to a country's public health goals. Since in some cases it may not be possible to precisely state the ALOP, as a temporary measure an ALOP could be reflected in a public health goal as an aim of reducing the number of cases in a population associated with a hazard in food.

5.2.2 Identification of available options

Risk management options are identified by countries. Codex may develop and recommend different risk management options (e.g., control programmes at the primary production, a commodity code of hygienic practice, use of HACCP, use of prerequisite / GHP programmes, performance criteria/standards and microbiological criteria/standards) for use by countries. Countries may also develop risk management options themselves.

Typically more than one measure is taken to achieve the desirable level of risk reduction and risk prevention.

The primary objective of microbiological risk management options assessment is an optimisation of the interventions necessary to minimize and to control microbiological risks. It is aimed at selecting the option or options that achieve the appropriate level of public health protection for the microbiological hazard in the commodity of concern in a cost effective manner as possible within the technical feasibility of the industry and other food/feed businesses.

The primary responsibility for compiling the list of available options lies with the risk manager in consultation with other stakeholders (e.g., academia, consumers, food scientists, industry and other food/feed businesses, regulatory authorities, etc.). However, risk assessors play an important role in this process by providing information that permits the objective evaluation and comparison of different risk management options.

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

As a general document, this section can only provide general guidance on which types of options are available and how they may be identified. Specific details with respect to hazard and/or commodity targeted options should appear in more specific Codex documents (e.g. Commodity Codes of Hygienic Practices, Codes of Practice, Risk Management Guidance documents such as "Guidelines for the Control of *Listeria monocytogenes* in Food").

There are usually many different options for reducing microbiological risks. Options recommended by Codex for implementation by countries or identified by countries may include :

- establishing standards, guidelines, codes of practice etc. including microbiological performance criteria and other criteria, e.g. process criteria;
- 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);
- labelling products with consumer information regarding additional guarantees of safety or information that either instructs regarding safe handling practices or warns regarding microbiological hazards that are likely to occur and for which adequate controls were unavailable;

- educating / informing the population at large or affected sub-groups about the steps they can take to reduce risks;

The following options are applicable only to countries :

- providing incentives to operators in the food chain to use specific management tools such as good husbandry practices, HACCP and GHP;
- establishing regulatory requirements and/or creating incentives for changes in attitudes that will contribute to risk reduction.

When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.

[For countries, in that case, it may be appropriate to adopt a precautionary approach in the microbiological risk management.]

5.2.2.1 Role of FSO

Recognizing the difficulty of relating control measures directly to an ALOP, the concept of Food Safety Objectives (FSOs) has been introduced. Implementation of food safety controls can greatly benefit from expression of the ALOP in terms of the required level of control of hazards in food. This is the basis of the FSO concept. The ALOP is an expression of a public health risk, while an FSO expresses the level of a hazard in relation to this risk.

A FSO is based on the fact that the risk characterisation curve of the MRA relates the health risk to the concentration of the hazard at the point of consumption. FSO's should be established for all important pathogens[9].

FSOs are seldom verifiable as regulatory standards as they occur at the point of consumption. They need to be translated by the competent authority to performance, process or microbiological criteria further up the food chain, in order to establish/maintain the level of control needed at other parts of the food chain. These criteria may constitute critical limits to CCPs in HACCP plans or the outcomes of a complete HACCP plan.

In most cases, the level of hazard at earlier stages of the food chain than consumption differs from the FSO e.g. if a FSO for *Salmonella* in fresh apple juice is a frequency of one in 100 servings, a desired outcome earlier in the chain may be specified as less than one in 10,000 servings. An MRA can assist in determining such relationships.

In countries FSOs can be used:

- By governments to communicate the expected level of food safety to the food industry and other food business and the consumers in relation to the appropriate level of protection or to encourage or direct change in the industry and enhance the safety of certain products. FSOs do not prescribe how the expected level of food safety can be achieved, leaving it, as may be appropriate, to the food industry and other food businesses to select the appropriate technology including the establishment of process criteria. But the FSO may require some operators to modify their operation, implement more effective technologies or adopt tighter control system. FSOs can also be used as a basis for performance criteria to be set by the governments.
- By the food industry to show that its products meet the established level of risk for the specified hazard.

FSOs implemented by countries for food in trade will not be universally common and will take into account national and regional situations

[9] it seems very important to complement this document by rating with respect to health hazard the different microbiological pathogens.

5.2.2.2 Performance criteria

For certain food-borne pathogens (e.g. *Salmonella*, *Campylobacter*), a cross contamination between raw materials and food ready to be eaten, plays an important role. Since FSO per definition only applies for products at the point of consumption, this concept is not applicable for the food safety problems linked to raw material. Consequently for these products, performance criteria may be used by governments to communicate standards or targets for process control.

Risk management for such products should focus on reduction of pathogen contamination in the early steps of production, especially reduction during animal rearing and slaughter would be the most effective approach.

In the ideal situation, a performance criteria will be set on the basis of a microbiological risk assessment (MRA). This will normally involve a use of an FSO (see below). However in most current food safety risk management situations, a MRA will not be available. In this case, performance criteria can be set according to available scientific information linking levels of hazard control at particular steps in the food chain with human illness.

Performance criteria can be established by governments andindustry and other food/feed businesses. Where set by governments performance criteria may be mandatory or targets for process control. As such, they provide flexibility in how industry complies with regulatory expectations e.g. use of validated process criteria in HACCP plans.

5.2.2.3 Microbiological criteria

As with performance criteria, microbiological criteria may be implemented as food safety measures using either GHP or HACCP approaches.

Microbiological criteria can be employed in risk management systems where it is important to verify the compliance of product on a lot-by-lot basis, or where the history of food is not known, e.g., imported foods, foods sampled at retail establishments. Microbiological criteria can also use as guidelines for process control, and in validation and verification of HACCP programmes. Microbiological criteria should be used with appropriate sampling plans and with a specific validated analytical method. Spreadsheets systems are available that allow determination of the performance of a particular sampling plan.

When HACCP is not employed, the use of microbiological criteria could be considered for use as a means to verify the on-going performance of the food safety control system.

5.2.2.3 Other factors

When considering microbiological risk management options, the use of other factors (e.g. economic costs, benefits, technical feasibility, and public risk reduction preferences, public values.) may be appropriate for countries in some risk management contexts, particularly in the determination of measures to be taken. Within Codex, when considering other factors, reference should be made to the Codex *Criteria for the Consideration of Other Factors in Relation to the Codex Statements of Principle on the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account*.

5.2.3 Selection of preferred microbiological risk management options

Once identified, potential options should be assessed by risk managers and by stakeholders. It is important to state that both countries and Codex develop and recommend risk management options. Risk management options developed by Codex are intended for implementation by countries. Final risk management option selection and implementation is carried out by countries.

In this assessment process, the protection of human health, based on scientific knowledge of the microbiological hazards and the understanding of the primary production, processing technology and handling during food preparation, storage and transport should be the primary consideration.

Food safety is the result of a continuum of control measures applied through the food chain. Risk management activities, if they are to be effective should consider the relevant methods and approaches to primary production and processing as well as the methods of transport, distribution and product storage. Provisions relating to such areas as inspectional procedures and methods of analysis and sampling should be considered.

However, other important elements should be considered, as appropriate. These elements could include other factors relevant to the health protection of consumers and promotion of fair practices in food trade, taking into account preferences expressed by stakeholders, including technical and economic feasibility, the availability of expertise cost effectiveness of alternative approaches to limiting risk consumers information, environmental impact and public values.

The selection of preferred microbiological risk management options should also consider whether an option may cause adverse consequences such asthe 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.

5.2.4 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;
- take into account the whole food chain from primary production to consumption;
- take into account, as appropriate, multiple sources of the hazard and multiple product types which may be involved;
- offer a choice, to the extent possible, between risk control options which achieve an appropriate level of public health protection;
- 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 into account appropriate and available production methods and process, inspection, sampling and testing methods as well difficulties concerning monitoring, inspection and requirements application;
- take account of the level of risk deemed appropriate by risk managers, considering all stakeholder preferences relevant for the health protection of consumers;
- include incentives for innovation, evaluation and research.

Taking into account the extent of scientific knowledge regarding the impact of the microbiological hazard in human health. When such knowledge is insufficient, more stringent control measures should be selected. This may be termed a precautionary approach to microbiological risk management.

For national purposes :

When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for a member government to exercise precaution by provisionally adopting measures to protect the health of consumers until additional pertinent scientific information available and a more complete risk assessment can be performed. In such situations, member countries should take into account the following considerations:

1) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost-effectiveness considerations.
2) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.
3) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data.
4) The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information. The measures taken are the least trade restrictive to achieve protection of the health of consumers.
5) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.
6) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.

6. GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

The actual implementation of microbiological risk management decisions is the responsibility of countries.

Implementation of the food controls decided on during assessment of risk management options can take many forms. A very wide range of food safety measures may be implemented, either alone or in combination, and these include development of regulatory standards, guidelines and related texts.

Implementation of food controls usually includes specification of the role of competent authorities in ensuring compliance with regulatory requirements, and enforcement actions that may result from non-compliance. Nevertheless, the primary responsibility for ensuring food safety rests with the food/feed businesses. The competent authority establishes standards etc. e.g. performance criteria, and verifies that they are met by industry, but industry primarily implement the measures that achieve standards.

6.1 IMPLEMENTATION OF STANDARDS, GUIDELINES AND RELATED TEXTS

Codex standards, codes of hygienic practice, codes of practice and guidelines provide specific control measures that can be utilized by countries, along with other control measure information, to establish a microbiological risk management system. The selection of which control measures to employ will depend on the microbiological hazard to be controlled, the commodity involved, the ALOP for the hazard in the commodity, and as appropriate, the specific FSO and performance criterion.

In selecting (and implementing) food controls, which may be based on FSOs, competent authorities should have assured their feasibility, and should be able to recommend how to implement these measures.

A decision may also be taken to adopt Codex standards, guidelines and related texts that are based on an "international" FSO that is acceptable at the national level.

6.2 IMPLEMENTATION OF FSOS AND PERFORMANCE CRITERIA

6.2.1 FSO

Use of a FSO (e.g., level of a pathogen in a commodity at the point of consumption does not exceed 100/org. gram) is a means by which a set of control measures can be shown to achieve the ALOP and a performance criterion. In this sense, it is a "bridge" between the ALOP and the control measures. If the control measures are shown to achieve the FSO, and previous work has demonstrated that the FSO achieves the ALOP, then it

can be assumed that if the FSO is achieved, the ALOP is met. FSOs may be used to select risk management control measures and to verify that selected control measures are operating properly.

If a quantitative FSO has been established, this may be the more practical means of determining the effectiveness of control measures, and thus in making risk management decisions regarding the use of specific control measures or control measure combinations. For example, determining whether a set of control measures meets a FSO of 100/g of a pathogen may be easier than assessing whether the same set of control measures achieves a given log reduction of the pathogen.

The availability of a FSO allows validation of performance criteria as appropriately contributing to the achievement of the required ALOP.

Ensuring the correct use of an FSO in the establishment of food safety measures is the responsibility of the competent authority and requires communication of the FSO to all interested parties.

6.2.3 Performance criteria

In a risk-based food control system, a performance criteria should be linked to the FSO / ALOP i.e. the level of hazard control required upstream of the FSO that achieves the ALOP.

Performance criteria (e.g., a "n" log reduction in the level of a pathogen, incidence of a pathogen in a product does not exceed a given percentage) are established to ensure that control measures selected achieve a country's appropriate level of protection for a microbial pathogen in a commodity. By matching the control achieved by a specific combination of control measures with the established performance criterion, the most appropriate control measures, i.e., those that are most technologically feasible and economic, that meet the ALOP, may be selected. Conversely, by matching the outcome of an existing set of control measures with the performance criterion, that specific set of control measures may be identified (verified) as capable of achieving the ALOP.

6.3 ROLE OF PRODUCT TRACING/TRACEABILITY:

Product tracing/traceability should facilitate the rapid withdrawal of unsafe food products and food ingredients from the market place when there is a public health threat. Product tracing/traceability is a food safety control measure and should be incorporated into microbiological risk management programmes, specifically as a component of food recall systems.

7. MONITORING AND REVIEW

An essential part of a risk management framework is the on-going gathering, analysing, and interpreting of data to determine how well risk management activities have performed and to determine what steps may need to be taken next to better improve public health. Monitoring and surveillance allows risk management strategies and food safety measures to be appropriately reviewed to show that: stated public health goals are being achieved, new food safety problems are identified as they emerge, and data is provided for future improvements in risk management strategies.

It is the responsibility of the risk manager to evaluate food safety risk management through the use of monitoring and review. This should be a periodic process, and will normally be the responsibility of national competent authorities. In most cases, monitoring and review of public health outcomes will be a measure of the effectiveness of regulatory food control programmes.

7.1 MONITORING

In most cases, monitoring and surveillance of human populations and the analysis of human health data is the responsibility of national competent authorities. However, international organizations such as the World Health Organization provide guidance for establishing and implementing public health monitoring programmes.

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

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

Where relevant, national monitoring and surveillance activities should be designed to collect information that will be of high utility in development of future risk management decisions, including information for undertaking microbiological risk assessments, e.g. provision of concentration as well as prevalence data for hazards in foods.

7.2 REVIEW

Review of risk management strategies and food safety measures is necessary to assess whether or not the risk management strategy as a whole, or a particular risk management action, is successful in achieving the desired results and appropriately contributing to consumer protection. In the broadest sense, monitoring of the consumer population may indicate that current risk management activities are not delivering acceptable public health goals, and more stringent measures may need to be implemented. In other situations, targeted monitoring may indicate that review of a particular food safety measure is necessary.

Risk management decisions should also be opened to review when new data becomes available that might substantively alter the conclusions of risk assessment or its associated degree of uncertainty. 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 patterns, changes in food processing patterns, as well as data from epidemiological studies and surveillance and monitoring programmes in relation with foodborne diseases.

Review of risk management decisions should also occur when new risk management options become available.

The results of reviews of risk management decisions should be made public and communicated to relevant interested parties.

For application by Codex :

On the basis of new data (see above), pertinent Codex subsidiary bodies should periodically review risk management standards, guidelines and recommendations to ensure that the guidance provided is adequate with respect to the known science and known control measure technology, or to address newly identified problems.

For application by countries :

On the basis of such data, risk management decisions may be re-evaluated to better address the microbiological public health problem, or to address newly identified problems. Further activities may be initiated e.g., collection of additional and more targeted information, establishment of new risk reduction goals, and the implementation of additional food safety measures.

With respect to governments, tools used to evaluate risk management processes may also include reviewing the effectiveness of the regulatory control programmes, and reviewing information relating to the effectiveness, cost, or unanticipated consequences of a particular technology. These reviews may change the risk management options and the final risk management decision.

New information should be compared to the information that was previously used by risk assessors and/or risk managers, to determine the likely impact on the microbiological risk assessment or the selection of a particular risk management option e.g. new information on food consumption patterns and food preparation

practices may indicate that certain population groups are at greater risk than previously thought, and assessment of risk management options will need to be revisited taking the new information into account.

Microbiological risk assessment allows risk managers to evaluate different production, processing and product handling scenarios. Each of these steps is comprised of specific food safety control measures. Microbiological risk managers, by asking risk assessors to determine the impact on the risk estimate for a specific pathogen in a product type(s) of varying specific control measures (e.g., process time and/or temperatures, pH adjustment, lowering of pathogen levels through the use of different wash/rinse procedures, product storage time at specific temperature(s)) can evaluate the impact of these control measures on the risk to which consumers may be exposed, and thus aid in the selection of the optimum control measures which are also technologically and economically feasible. The impact of different performance criteria and/or FSOs on the risk estimate may also be undertaken (e.g., the impact of 100 org/g vs. 1000 org/g). Thus, use of microbiological risk assessment will help to interrelate the impact of food safety control measures on achieving performance criteria and/or FSOs (and the reverse), aiding in the selection of the most appropriate risk management control options.

Monitoring and review in the sense developed above is a governmental function. Industry may be required to respond if human data shows inadequate risk management and can suggest the review of risk management measures. With respect to industry, tools used to evaluate the risk management process may include reviewing the effectiveness of HACCP and its pre-requisite programmes, 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.

ANNEX 1: SUGGESTED ELEMENTS FOR A MICROBIOLOGICAL RISK PROFILE

1. **Pathogen-food commodity combination(s) of concern**

   - Pathogen(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 pathogen have been associated.

2. **Description of the public health problem**

   - Description of the pathogen 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 and any differences according to regional and seasonal variations
     - Outcome of exposure
     - Severity of clinical manifestations
     - Case-fatality rate
     - 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 influence foodborne transmission of the pathogen
     - Foods implicated
     - Frequency and characteristics of foodborne outbreaks
     - Frequency and characteristics of foodborne sporadic cases
     - Epidemiological data from outbreak investigations
   - 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 programmes, and public health intervention programmes (e.g., vaccines)

4. **Other Risk Profile Elements**

- Regional differences in the incidence of food borne illness due to the pathogen
- 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 risk management guidance

5. Risk Assessment Needs and Questions for the Risk Assessors

- Based on the risk profile, identify whether a microbiological risk assessment is appropriate to fulfill the desired CCFH output(s). Provide initial recommendations on the desired outputs of such a risk assessment and how it would be used by CCFH.
- If a risk assessment is identified as being needed, identify initial suggested questions for CCFH (as the risk managers) to address to the Joint FAO/WHO Joint Expert Group (as the risk assessors) to permit them to respond to the request from CCFH.

6. Available Information and Major Knowledge Gaps

Provide, to the extent possible, information on the following.

- Existing national risk assessments on the pathogen/commodity combination(s) including, if possible,
- Other relevant scientific knowledge and data that would facilitate risk management activities including, if warranted, the conduct of a risk assessment.
- Existing Codex risk management 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 Codex risk management guidance
- Sources (organizations, individual) of information and scientific expertise that could be used in developing Codex risk management guidance.
- Areas where major absences of information exist that could hamper risk management activities including, if warranted, the conduct of a risk assessment.

ANNEX 2

Figure: Decision chart for [preliminary] risk management activities in relation to an overall framework for managing food-borne risks to human health; taken from Kiel expert consultation of April 2002)