

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 5 (a)

CX/FH 04/5

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

#### PROPOSED DRAFT PROCESS BY WHICH THE COMMITTEE ON FOOD HYGIENE COULD UNDERTAKE ITS WORK IN MICROBIOLOGICAL RISK ASSESSMENT/RISK MANAGEMENT

**Prepared by the United States of America in collaboration with Australia, Canada, France, Germany, India, Ireland, Japan, New Zealand, the Netherlands, Sweden, the United Kingdom, the Commission of the European Community, Food and Agriculture Organization, and World Health Organization.**

Governments and interested international organizations are invited to submit comments or information on the attached Proposed Draft Discussion Paper and should do so in writing **to:** Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, 1400 Independence Avenue, S.W., Washington DC, 20250 USA, preferably by email: [syed.ali@fsis.usda.gov](mailto:syed.ali@fsis.usda.gov) or fax: 1 (202) 720-3157, with a copy **to:** Secretary, Codex Alimentarius Commission, FAO, viale delle Terme di Caracalla, 00100 Rome, Italy, by email: [codex@fao.org](mailto:codex@fao.org) or fax: +39 (06) 5705.4593 **before February 1, 2004**

#### INTRODUCTION

The Codex Committee on Food Hygiene (CCFH) is moving towards a broad risk management-based approach to developing recommendations on ensuring consumer protection and facilitating fair practices in food trade. This broad risk-management approach may employ microbiological risk assessment and may utilize a spectrum of risk management or risk communication work products including guidance documents, codes of hygienic practice, food safety objectives and microbiological criteria.

The Codex Alimentarius Commission recognized this change in the Committee's operation by adopting, at its 24<sup>th</sup> Session, two additional Terms of Reference for the Committee. Specifically, these are:

- ◆ To suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessor.
- ◆ To consider microbiological risk management matters in relation to food hygiene and in relation to the microbiological risk assessment activities of FAO and WHO.

The Committee recognized that the process of initiating work, preparing a microbiological risk assessment and developing a risk management strategy is a complex process, involving CCFH, the FAO/WHO Joint Expert Group on Microbiological Risk Assessment (JEMRA) and specific member countries. The Committee also recognized that a structured, yet flexible process was needed to initiate and carry out this work in a timely, orderly and complete fashion. The Committee, at its 34<sup>th</sup> Session, considered a Document (CX/FH 01/5 – Add.2) on a “*Proposal for a Process by which the Codex Committee on Food Hygiene Could*

*Undertake Its' Work in Microbiological Risk Assessment/Risk Management* originally submitted by the United States as a Conference Room Document at the 33<sup>rd</sup> Session of CCFH.

The Committee agreed that establishing a process in regards to undertaking its work on microbiological risk management was beneficial and invited the United States to prepare a Discussion Paper on the subject for the Committee's consideration at its 35<sup>th</sup> Session.

During the 35<sup>th</sup> Session, CCFH requested the United States to revise the described process concerning work related to risk management so that it was simple, short, and flexible as possible. It was agreed that the revised document should be circulated for further consideration and pending the outcome of the discussions be considered for inclusion in the Codex Alimentarius Procedural Manual. A drafting group consisting of the United States of America in collaboration with Australia, Canada, India, Ireland, France, Germany, Japan, New Zealand, the Netherlands, Sweden, the United Kingdom, the Commission of the European Community, Food and Agriculture Organization, and World Health Organization was established to assist in the revision of the document.

This Discussion Paper presents a proposed process by which CCFH might undertake its microbiological risk management activities. The Paper also presents in Annex 1, "Suggested Elements to Include in a Microbiological Risk Management Risk Profile."

## **PROPOSED PROCESS<sup>1,2</sup>**

The proposed process is outlined in detail in Sections 1.0 to 5.0 and includes the following steps.

- Development of a proposal (e.g., risk profile) for the Committee to undertake new work in risk management (see Section 1.0).
- Review the risk profile and the scientific issues underlying the proposed work (see Section 2.0).
- Acceptance or denial of the proposal for new work (see Section 2.3). The relative priority of the work will be established based on the work priority setting procedures adopted by CCFH.
- Establishment of a working group to assist the Committee in undertaking the new work (optional).
- Undertaking a microbiological risk assessment through the FAO/WHO Joint Expert Group on Microbiological Risk Assessment (optional) (see Sections 3.0 and 4.0).
- Development, if warranted, of a new CCFH microbiological risk management guidance document or amendments to existing codes of hygienic practices or codes of practice (see Section 5.0).

### ***1.0 Proposal for Work***

1.1 New work relating to microbiological risk management may be proposed by the Codex Alimentarius Commission, by CCFH upon its own initiative, by another Codex subsidiary body upon referral to CCFH, by an individual country or countries, or by a recognized international intergovernmental or non-governmental organization. Normally, this proposal for work will involve a specific microbial pathogen(s)/commodity (commodities) combination or a code of hygienic practice for a commodity class or activity (e.g., produce, bulk transport).

1.2 The following criteria, as appropriate, should guide the development of a proposal for new work.

- The issue is a significant public health problem in terms of the number and/or severity of human illness.

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<sup>1</sup> The use of the term CCFH or "the Committee" refers to the Codex Committee on Food Hygiene.

<sup>2</sup> It is intended that this procedure for proposing new work will be consistent with the project document proposal approach to undertake new work as outlined in the report of the 19<sup>th</sup> Session of CCGP (ALINORM 04/27/33).

- The issue has a large geographic distribution. Particular emphasis should be given to problems affecting both developing and developed countries and/or problems associated with international trade.
- There is sufficient scientific knowledge available to provide scientifically sound guidance.

1.3 If the proposed new work will benefit from an international risk assessment to be conducted by the FAO/WHO JEMRA, the following information should be considered.

- The availability of sufficient scientific knowledge and data to conduct the needed risk assessment.
- There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to the control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance document.
- Availability of risk assessments performed at regional, national, and multinational levels that can facilitate the conduct of an international risk assessment.

1.4 Ideally, a proposal for new work should be provided to the Committee in written form in sufficient time to be included in the formal agenda of the CCFH meeting at which the nominator wishes to have the proposal considered. The proposal would normally be a brief request for work that should include responses to the criteria noted in 1.2 above and should, preferably, also contain a risk profile that includes the elements given in Annex 1, and the recommended work to be undertaken by the Committee (e.g., new microbiological risk management guidance document, amendments to an existing hygiene text). If a proposal for new work is presented to the Committee as a verbal request, the country/organization requesting the work should be prepared to provide the Committee with supporting equivalent information during the Committee's consideration of the request for new work.

1.5 The Committee recognizes that in undertaking risk assessment/risk management work, the Committee will normally serve as the risk managers and the FAO/WHO JEMRA will serve as the risk assessors.

1.6 In undertaking its microbiological risk management work, the Committee should follow the structured approach given in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development).

1.7 The Committee recognizes its need to develop risk management guidance in a timely fashion, whereas the time requirements often associated with the development of complex risk assessments can often be substantial. The Committee may, based on preliminary risk profile information submitted, request that FAO/WHO initiate appropriate microbiological risk assessment activities while still defining the specific risk management questions that will be evaluated by the risk assessment. Likewise, the Committee may schedule its work so that those sections of a new microbiological risk management guidance document that are not dependent on the risk assessment are being developed simultaneously with the risk assessment.

## ***2.0 Development of a Risk Profile and Agreement to Proceed with the Work***

2.1 The Committee has historically used Discussion Papers to consider new work, a process that often took several years. As a means of accelerating this process, a Risk Profile will be used as a means of proposing new risk management work to be undertaken by the Committee. The Risk Profile can be viewed as an abbreviated Discussion Paper that lays out the key elements of a microbiological risk management concern. The purpose of the Risk Profile to facilitate decision-making on the part of the Committee in relation to the need and scope of the proposed work. As such, the Risk Profile will typically be used at a single session of the CCFH. The elements of the Risk Profile are outlined in Annex 1 of this document. In brief, a Risk Profile describes: 1) the pathogen and food commodity combination(s) of interest; 2) the public health problem; 3) the current state of knowledge regarding relevant food production, processing, distribution, and consumption practices; 4) risk assessment needs and risk management questions; 5) available information and knowledge gaps; and 6) a recommendation for work and the type of Committee documents required (e.g., risk management control guidance document, code of hygienic practice, code of

practice, amendments to existing Codex hygiene texts, establishment of microbiological criteria or food safety objectives). It is expected that the material provided within the Risk Profile will prove useful in further considering microbiological risks during the subsequent development of the proposed microbiological risk management guidance document.

2.2 The Committee will review the Risk Profile at its earliest opportunity (usually at the next Session of the Committee), and decide whether or not the proposed work fulfills the established criteria (see Section 1.2 and the Criteria for the Establishment of Work Priorities<sup>3</sup>) and priorities for new work. The Committee will make a determination as to whether or not to proceed with the work suggested in the Risk Profile, including, as appropriate, requesting the undertaking of a microbiological risk assessment by the FAO/WHO JEMRA.

2.3 The Committee may conclude that it cannot reach a decision based on the Risk Profile. In such instances the Committee can request that the proposing member submit a more detailed Discussion Paper, following the format that has been historically used to introduce new potential areas of endeavour. Such a Discussion Paper would be re-introduced at a subsequent Committee meeting.

2.4 If the Committee concludes new work is needed, the Committee will recommend to the Codex Alimentarius Commission the initiation of the new work item.

### **3. *Involvement of the FAO/WHO Joint Expert Group on Microbiological Risk Assessment When a Risk Assessment is Deemed Necessary to Develop a Risk Management Strategy***

3.1 As stated in Section 2, the Committee will utilize the FAO/WHO JEMRA to conduct the risk assessments proposed and agreed upon. Not all risk management activities recommended in a Risk Profile will require a risk assessment.

3.2 The Committee will forward a request to FAO/WHO to undertake a specific microbiological risk assessment(s) and provide the JEMRA with the Risk Profile document, a clear statement of the purpose and scope of the risk assessment, any time constraints facing the Committee that could impact the risk assessment, and the specific risk management questions to be addressed by the risk assessors. FAO/WHO will inform the Committee of its agreement to carry out such work. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g., lack of data, lack of financial resources).

3.3 The Committee recognizes that an iterative process between risk managers and risk assessors is essential for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s). The iterative process is described in Section 4 of this document.

3.4 The FAO/WHO will provide the results of the microbiological risk assessment(s) to the Committee in a format and fashion to be determined jointly by the Committee and the FAO/WHO Joint Expert Group. As needed, the FAO/WHO will provide scientific expertise at Committee session or working groups to provide guidance on the appropriate interpretation of the risk assessment.

3.5 Unless jointly agreed upon otherwise, microbiological risk assessments carried out by the FAO/WHO JEMRA will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 020-1999).

### **4 *Iterative Process between CCFH and FAO/WHO Expert Joint Group for the Conduct of Microbiological Risk Assessments***

4.1 As stated in Section 3, the Committee recognizes that an iterative process between risk managers and risk assessors is essential for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s). In particular, dialogue between the Committee and FAO/WHO is desirable to thoroughly assess the feasibility of the risk assessment and ensure that the risk management questions posed by the Committee are

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<sup>3</sup> Codex Alimentarius Commission, *Procedural Manual*, p. 60 12<sup>th</sup> edition, 2001.

understood and addressed appropriately. If FAO/WHO agrees that the requested risk assessment proposed in the Risk Profile is feasible (see Annex 1, item 5) and will be undertaken, a series of planned interactions between the FAO/WHO JEMRA and the CCFH Working Group established for the risk assessment should be scheduled to assure effective communication. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees or other FAO/WHO risk assessment bodies, these committees should be included into the iterative process.

4.2 It is essential that communications between these entities are timely, facile and effective. To increase the timeliness of its work, the Committee will typically establish a Working Group and/or other communication mechanisms (e.g., drafting groups, electronic bulletin boards) to provide for communication between the Committee and risk assessors between sessions of CCFH. Any intermediary (i.e., Working Group) assigned by the Committee to serve as a liaison with the FAO/WHO JEMRA will need to report the progress and facilitate decision making in both a timely and effective manner so that progress in the development of a risk assessment (and the CCFH work products derived from it) is not unduly delayed.

4.2.1 The Committee and/or its liaison (i.e., the Working Group) are likely to receive questions from the JEMRA relating to the requested microbiological risk assessment(s), and will need to provide timely, appropriate responses. The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the risk management control options to be considered, key assumptions to be made regarding the risk assessment, and the analytical strategy to be employed in the absence of key data needed to perform the risk assessment.

4.2.2 Likewise, the Committee and/or its liaison (i.e., the Working Group) may pose questions to the JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop and/or understand the risk management control options selected.

4.3 The Committee may elect to discontinue or modify work on a risk assessment if the iterative process demonstrates that the ultimate risk management document is not feasible or warranted in light of the risk management decisions that have to be reached<sup>4</sup>, or that the completion of an adequate risk assessment is not feasible at the current time.

## 5. *Development of CCFH Microbiological Risk Management Guidance Documents*

5.1 The Committee should determine, at an early stage, the expected nature of the document(s) (or modifications to existing documents) that will be the result of its risk assessment/risk management work. The development of the document can then proceed through the normal Codex step process which would typically include a more detailed consideration of risk and the options available for their mitigation.

5.2 The document could take the form of traditional CCFH work products such as a code of hygienic practice, a code of practice, or amendments to existing Codex hygiene texts. Alternatively, effective articulation of risk management guidance in some instances may require an alternate format specifically directed at consideration of risk management strategies (see Section 5.4). Guidance may take the form of a formal confirmation that no change in current approaches is recommended. The type of document(s) or the need for it may be modified based on the risk assessment and the iterative process between the Committee and the FAO/WHO JEMRA. Likewise, in those instances where a risk assessment is not undertaken, the more detailed examination of risk that would occur during the development of a risk management document may require a re-consideration of need for the risk management guidance document or the type of document being developed.

5.3 The microbiological risk management guidance documents developed as a result of this process should be consistent with the frameworks, protocols, practices and criteria already established for the development of CCFH documents. In this regard, reference, as appropriate, should be made to the following Codex texts: *Principles and Guidelines for the Conduct of Microbiological Risk Management* (document in preparation); *Recommended Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997), individual Codex Codes of Hygienic Practice and Codes of Practice; and the *Principles for the*

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<sup>4</sup> See report of the 18<sup>th</sup> Session of CCGP “Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius” (ALINORM 03/33A, page 39, section 10).

*Establishment of and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997). In addition to the development of new documents, a microbiological risk management guidance document may also include modification to existing documents such as the inclusion of new annexes.

5.4 The CCFH document(s) will normally be entered into and proceed through the Codex Step Procedure and form guidance from Codex to its Members.

5.5 In addition to the traditional guidance documents developed by the Committee to assist member nations in the control of food safety risks (e.g., codes of hygienic practices), it is envisioned that the new risk analysis framework may require an alternative document format that would be used when developing guidance to describe risk mitigation strategies. The following are recommended as the likely elements for inclusion in such a microbiological risk management guidance document.

**Introduction and Background:** This section should include an initial statement of the food safety problem. This section should also include the rationale and justification for the work and the Committee's previous consideration and work on the subject. Included in this section can be summary information on the pathogen/commodity of concern, the effected populations and related information.

**Scope:** A short statement on the microbiological pathogen(s)/commodity (commodities) to which the risk management guidance applies.

**Risk Evaluation:** A comprehensive description of the food safety problem associated with the pathogen(s)/commodity combination(s). This section will include many of the elements articulated in the initial Risk Profile (see Annex 1) used to propose undertaking the development of the document including consideration of key scientific and technological factors affecting the risk.

**Consideration of the Risk Assessment:(Optional)** Consideration and interpretation of the results of a risk assessment carried out by FAO/WHO JEMRA at the request the Committee. Additional risk assessments conducted at a national level may also be considered in this section.

**Risk Management Options:** This section should present options available for managing the risk from the pathogen/commodity combinations(s) over the entire food chain. Within CCFH, this will typically take the form of a guidance document, such as a Code of Hygienic Practice, that articulates one of more "best practices" that will be widely accepted as successful GHP or HACCP strategies for managing microbiological food safety risks. Member countries can then use this guidance to develop specific risk management options that consist of one or more control measures (e.g., guidance for primary production, processing requirements, handling requirements during distribution and marketing, consumer education programs), instituted to control the microbiological food safety hazard, that are consistent with their specific conditions and requirements. Broad information on the types of risk management options can be found in the *Codex Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development). Information should be presented in sufficient detail to enable development and implementation of food safety programs that adequately control the risk arising from the microbiological pathogen/commodity. Whenever possible, multiple risk management options that achieve the desired level of risk mitigation should be identified as a means of providing flexibility in foods safety control strategies. The use of annexes is recommended to present detailed commodity related risk management control options. If appropriate, Food Safety Objectives, performance criteria and microbiological criteria may be included in this section. The evaluation of risk management options should consider the specific needs and capabilities of developing countries.

**Implementation:** Implementation of microbiological risk management options is the responsibility of national governments and industry. As appropriate, specific recommendations for the implementation of risk management options may be provided, particularly in relation to international trade.

**Monitoring and Review:** This section provides guidance on potential strategies for validating and verifying the effectiveness of risk mitigation strategies including the identification of potential metrics that can be used to assess successful, continuing implementation. Information specific and pertinent to the monitoring and review of the specific pathogen/commodity combinations(s) addressed in the guidance document should be provided. Whenever possible, multiple strategies for effective monitoring and review should be provided so

that member countries can identify strategies most pertinent to their requirements and conditions. If there are no specific recommendations unique to the pathogen/commodity combination(s), only a reference to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development) is needed. Where possible, monitoring and review should include guidance on potential metrics that can be used to assess of the impact of the food control measures on public health.

## ANNEX 1

**SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK MANAGEMENT RISK PROFILE****PURPOSE**

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

**SCOPE AND RATIONALE**

Identify the food safety issue (microbial pathogen(s)/commodity (commodities) of concern and provide information required by the Codex Committee on Food Hygiene to make an informed decision on the need to undertake work on the subject. This should include the rationale for the work (e.g., excessive incidence of disease, need to provide an international set of scientifically established risk management control measures). This section should address the criteria established by CCFH for undertaking new work in microbiological risk management.

**RISK PROFILE ELEMENTS**

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

**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
  - Outcome of exposure
  - Severity of clinical manifestations (e.g., case-fatality rate, rate of hospitalization)
  - Nature and frequency of long-term complications
  - Availability and nature of treatment
  - Percentage of annual cases attributable to foodborne transmission
- Characteristics of the foodborne transmission
  - Epidemiology and etiology of foodborne transmission, including characteristics of the food or its 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
- Regional, seasonal, and ethnic differences in the incidence of food borne illness due to the pathogen



- Economic impact or burden of the disease if 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
- Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines)
- Identification of additional risk mitigation strategies that could be used to control the hazard

### **4. Other Risk Profile Elements**

- The extent of international trade of the food commodity
- Existence of regional/international trade agreements and how they may affect the public health impact with respect to the specific hazard/commodity combination(s)
- Public perceptions of the problem and the risk
- Potential public health and economic consequences of establishing Codex microbiological risk management guidance document

### **5. Risk Assessment Needs and Questions for the Risk Assessors**

- Initial assessments of the need and benefits to be gained from requesting a microbiological risk assessment, and the feasibility that such an assessment could be accomplished within the required time frame
- If a risk assessment is identified as being needed, recommended questions that should be posed by CCFH to the FAO/WHO JEMRA

### **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, regulations, guidance documents) that could be considered in developing a Codex microbiological risk management guidance document
- Sources (organizations, individual) of information and scientific expertise that could be used in developing a microbiological risk management guidance document.

**RECOMMENDATIONS**

Summarize the action that is being proposed as new work by CCFH including:

- Specifying the type of work product that should be undertaken
  - Modification of existing risk management guidance documents
  - Development of a new microbiological risk management guidance document
- Identifying whether a request for a risk assessment will be necessary and beneficial
- Articulating the relative urgency of the risk management concern, time constraints, and other factors that will influence the priority that the Committee will give to the proposed new work