

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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WORLD  
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Agenda Item 5 (e)

CX/FH 03/6

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, Florida, United States of America, 27 January – 1 February 2003

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

(Prepared by the United States of America)

Governments and interested international organizations are invited to submit comments or information on the attached Proposed Draft Process 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 15 November 2002.**

## 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 tools including microbiological risk management 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.

At the 34<sup>th</sup> Session of CCFH, the Committee agreed to continue and/or initiate work on the following microbial pathogen/commodity combinations which will and/or could lead to specific output documents.

- ❑ *Listeria monocytogenes* in ready-to-eat foods
- ❑ *Salmonella enteritidis* in eggs
- ❑ *Salmonella spp.* in broilers (chickens)
- ❑ *Campylobacter spp.* in broilers (chickens)
- ❑ *Vibrio spp.* in seafood
- ❑ *Enterohemorrhagic E. coli* in ground beef and other foods to be determined

This work has entailed or will entail the development of risk profile information, has or is likely to involve the undertaking of microbiological risk assessments by the FAO/WHO Joint Expert Group and is expected to result in output documents (e.g., risk management guidance document, code of hygienic practice) from CCFH or other Codex committees or bodies.

The Committee recognized that the process of initiating work, preparing a microbiological risk assessment and developing an output document is a complex process, involving CCFH, the FAO/WHO Joint Expert Group on Microbiological Risk Assessment and specific member countries. The Committee also recognized that a structured, yet flexible process was needed to 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 assessment/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.

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

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

The proposed process includes the following steps.

- Consideration and acceptance of a proposal to undertake new work relating to microbiological risk assessment/risk management.
- 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).
- Carrying out an iterative process between CCFH (as risk managers) and the FAO/WHO Joint Expert Group (as risk assessors) to clarify such issues as scope, assumptions and the impact of the use of different microbiological risk management options.
- Development, if warranted, of a microbiological risk management guidance output document or amendments to existing codes of hygienic practices or codes of practice.

### **1.0 Proposal for Work**

1.1 New work relating to microbiological risk assessment/risk management may be proposed by the Codex Alimentarius Commission, by CCFH upon its own initiative, by another Codex subsidiary body

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

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.

1.2 The following criteria should guide the development of a proposal for new work.<sup>2</sup>

- The issue is a significant public health problem in terms of the number and/or severity of human illness.
- The issue is a problem in both developing and developed countries.
- The issue is a problem in international trade.
- There is sufficient scientific knowledge available to provide scientifically sound guidance.

1.3 If the proposal for new work is going to include a recommendation for the conduct of an international risk assessment, additional criteria for that phase of the new work should include

- Data are available to conduct risk assessment.
- There is a reasonable expectation that a risk assessment will be reasonably likely to provide results that can assist in reaching risk management decisions related to the control of the microbiological hazard.
- A risk assessment has been initiated at the national level in accordance with the criteria set forth in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 020-1999).

1.4 A proposal for new work should, preferably, be provided to the Committee in written form. 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, in abbreviated form, a risk profile following the risk profile elements given in Annex 1, and the recommended work output of the Committee (e.g., microbiological risk management control guideline document, code of hygienic practice, amendments to existing hygiene texts). 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. The request for new work may also be in the form of a Discussion Paper as presented in Section 2.

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 Joint Expert Group on Microbiological Risk Assessment will serve as the risk assessors.

1.6 In undertaking its microbiological risk management work, the Committee should normally 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 the need to develop risk management guidance in a timely fashion and the time requirements often associated with the development of complex risk assessments. While awaiting the development of a Discussion Paper, the Committee may, based on preliminary risk profile information submitted, request WHO/FAO to initiate appropriate microbiological risk assessment activities.

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<sup>2</sup>Criteria for undertaking new microbiological risk assessment/risk management work were agreed upon by CCFH at its 32<sup>nd</sup> Session (see Report of the 32<sup>nd</sup> Session of CCFH, ALINORM 01/13, paragraph 17). The United States believes that additional clarity is needed in separating risk assessment and risk management, and that there needs to be sufficient information to both prepare the risk management guidance document(s) and to carry out the needed risk assessment(s). The United States suggests, therefore, that the criteria be revised as indicated.

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

2.1 The Committee will review the proposal for work and decide whether or not it fulfills the criteria (see Section 1.2 and the Criteria for the Establishment of Work Priorities<sup>3</sup>) and priorities for new work. If the Committee decides the subject warrants the Committee committing its time and resources, the Committee will normally request the development of a Discussion Paper on the proposal. The Committee may utilize a Working Group to assist in the development of the Discussion Paper.

2.2 In order that the Committee may complete its work in a timely fashion, it would be expected that the Discussion Paper would be used as the basis for the Committee's output document (particularly for risk management guidance documents).

2.3 The Discussion Paper will normally take the form of a Risk Profile, or will include the elements of a Risk Profile. The usual elements to include in the Discussion Paper/Risk Profile are given in Annex. 1. The Discussion Paper should also include, as appropriate: 1) the recommendation to conduct a microbiological risk assessment, if such a risk assessment is considered appropriate; and 2) recommended form(s) of output for the work (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).

2.4 The Committee will review the Discussion Paper at its earliest opportunity (normally at the next Session of the Committee) and make a determination as to whether or not to proceed with the work, including, as appropriate, requesting the undertaking of a microbiological risk assessment by the FAO/WHO Joint Expert Group and the recommended output(s)/document(s).

2.5 The Committee will recommend to the Codex Alimentarius Commission the initiation of new work items as agreed upon by the Committee.

## **3. Involvement of the FAO/WHO Joint Expert Group on Microbiological Risk Assessment**

3.1 The Committee will utilize the FAO/WHO Joint Expert Group on Microbiological Risk Assessment (and any future permanent FAO/WHO body established to carry out this function) as the microbiological risk assessors to undertake any microbiological risk assessments that may be required and agreed upon.

3.2 The Committee will forward a request to WHO/FAO to undertake specific microbiological risk assessment(s) and provide the WHO/FAO Joint Expert Group with the Discussion Paper (or preliminary documents) pertinent to the risk assessment. WHO/FAO will inform the Committee of its agreement to carry out such work. If a decision is made by WHO/FAO not to perform the requested risk assessment, WHO/FAO 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 WHO/FAO 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.

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

3.4 Unless jointly agreed upon otherwise, microbiological risk assessments carried out by the FAO/WHO Joint Expert Group will utilize the process 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 Group on Microbiological Risk Assessment**

4.1 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 work outputs.

4.2 To increase the timeliness of its work, the Committee may utilize Working Groups to develop output documents and to provide for communication between the Committee and risk assessors between Sessions of CCFH.

4.3 The Committee will provide the FAO/WHO Joint Expert Group with the Discussion Paper/Risk Profile developed by the Committee in undertaking its work on the specific microbial pathogen(s)/commodity (commodities) combination.

4.4 The Committee and/or its Working Group will receive from and respond to questions from the Joint Expert Group relating to the microbiological risk assessment(s). 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 need for additional data to perform the risk assessment.

4.5 The Committee and/or its Working Group may similarly initiate questions that it addresses to the risk assessors to clarify, expand, or adjust the risk assessment to better develop and/or understand the risk management control options selected.

4.6 This iterative process will often result in multiple communications between the Committee and the FAO/WHO Joint Expert Group. Recognizing the importance of completing microbiological risk assessment/risk management work in a timely fashion, this interaction should be done as expeditiously as possible.

4.7 The Committee may elect to discontinue work on a specific microbiological pathogen/commodity combination(s) if the iterative process demonstrates that the ultimate risk management output is not feasible or warranted.

#### **5. Development of CCFH Output Document(s)**

5.1 The Committee should determine, at an early stage, the expected nature of the output document(s) that will be the result of its' risk assessment/risk management work on a specific microbiological pathogen/commodity combination(s). The output could take the form of risk management guidelines to control the microbial pathogen(s) in the applicable commodity (commodities), a code of hygienic practice, a code of practice, or amendments to existing Codex hygiene texts. It may also take the form of a recommendation to take no action. Microbiological criteria or food safety objectives may be included in the risk management guidance. The output document(s) may be modified based on the risk assessment and the iterative process between the Committee and the WHO/FAO Joint Expert Group.

5.2 The risk management 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 Establishment of and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997).

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

5.4 The following are recommended elements for inclusion in 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 Profile:** A comprehensive description of the food safety problem associated with the pathogen(s)/commodity combination(s). Utilize the Risk Profile elements presented in Annex 1 to develop this section of the Document.

**Consideration of the Risk Assessment:** A presentation of the results of risk assessments carried out pertinent to the food safety problem, particularly risk assessments carried out on the pathogen/commodity combination(s) of concern.

**Risk Management Options:** This section should present options available for managing the risk from the pathogen/commodity combinations(s) over the entire food chain. 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 countries to develop and implement food safety programs that adequately control the risk arising from the microbiological pathogen/commodity. As appropriate, preferred options should be identified. The use of annexes is recommended to present detailed commodity related risk management control options. As appropriate, Food Safety Objectives, performance criteria and microbiological criteria may be included in this section.

**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.

**Monitoring and Review:** Information specific and pertinent to the monitoring and review of the specific pathogen/commodity combinations(s) addressed in the guidance document should be provided. 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.

## RECOMMENDATION

The Committee is invited to comment on the proposed process by which CCFH can undertake its work in microbiological risk assessment/risk management and to recommend the appropriate mechanism to establish the process (e.g., inclusion in the *Codex Procedural Manual*).

## ANNEX 1

**SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK  
MANAGEMENT DISCUSSION PAPER/RISK PROFILE****SCOPE AND RATIONALE**

Identify the food safety issue (microbial pathogen(s)/commodity (commodities) of concern and provide sufficient evidence of the need for the Codex Committee on Food Hygiene to undertake work on the subject including 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 assessment/risk management.

**RECOMMENDED OUTPUTS**

Specify an initial output document(s) that the Committee would develop; this may be a risk management guideline control document, a code of hygienic practice, an amendment to an existing Codex hygiene text, or some other form of risk management guidance. An initial output may also be a recommendation that CCFH review existing risk assessment/risk management information with respect to existing Codex hygiene texts to determine what, if any, additional work needs to be done. Alternatively the risk profile may determine that no output or risk assessment is necessary.

**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 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 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
- Economic impact or burden of the disease if readily available.
  - Medical, hospital costs

- Working days lost due to illness, etc.

### **3. Food Production, processing, distribution and consumption**

- Characteristics of the commodity (commodities) that are involved and that may impact on risk management
- Description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices).
- What is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects.
- Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines)

### **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.