

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of  
the United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 8

CX/FH 11/43/8  
October 2011

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

#### 43<sup>rd</sup> Session

Miami, Florida, United States of America, 5-9 December 2011

### DISCUSSION PAPER ON THE REVIEW OF THE RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE

(Prepared by the Delegation of the European Union)

#### BACKGROUND

1. The 26<sup>th</sup> Session of the Commission adopted the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and requested all Codex Committees to develop or complete specific guidelines on risk analysis in their respective areas for inclusion in the Procedural Manual<sup>1</sup>. The Codex Committee on General Principles was tasked to ensure coordination of work and consistency with overarching Working Principles.
2. During the 39<sup>th</sup> Session of CCFH (November 2007), the Secretariat recalled the request from the Commission to the Committee to develop a Risk Analysis Policy document to guide its work as part of the Codex Strategic Plan. Although the deadline for review of such work by the Executive Committee was 2013, the Secretariat suggested to the Committee to begin this work as soon as possible so as to ensure there was adequate time for development of the document<sup>2</sup>. The Committee accepted the offer of the Delegation of India to lead the work on the development of the Risk Analysis Policy of the CCFH and agreed that the work would proceed via electronic working group in future. Australia, Brazil, Canada, the European Union, France, Finland, Germany, Japan, Peru, the Philippines, Thailand, United States of America, FAO and WHO expressed their interest in contributing to that work.
3. At the 40<sup>th</sup> session of CCFH, noting the decision of the CAC regarding Activity 2.1 of the Codex Strategic Plan 2008-2013 (Review of consistency of risk analysis principles elaborated by the relevant Codex Committees) and the decision of the previous session of CCFH on the work to elaborate a risk analysis policy document to guide CCFH work, the Committee encouraged the Delegation of India to proceed with this work in order to consider the above document at its next session<sup>3</sup>.
4. At the 41<sup>st</sup> session of CCFH, on the basis of the work carried out by the Delegation of India and following an in-session working group, the Committee further agreed on amendments and forwarded the Proposed Draft Risk Analysis Principles and Procedures Applied by CCFH to the 33<sup>rd</sup> Session of the Commission for adoption and subsequent inclusion in Section VI of the Codex Alimentarius Procedural Manual<sup>4</sup>. However the Committee noted that some inconsistencies might exist between the main document on Risk Analysis Principles and Procedures and the Annex on the process by which the Codex Committee on Food Hygiene undertakes its work and agreed to ask the CCGP to take care of these inconsistencies while reviewing these texts. Following some debate on possible amendments, the 26<sup>th</sup> session of CCGP finally

<sup>1</sup> ALINORM 03/41 para. 142-148

<sup>2</sup> ALINORM 08/31/13 para. 161-162

<sup>3</sup> ALINORM 09/32/13 para.15

<sup>4</sup> ALINORM 10/33/13 para. 139-150

agreed to endorse the document as proposed by CCFH<sup>5</sup>. These principles and procedures were included in the Section IV Risk Analysis of the Procedural Manual following adoption by the 33<sup>rd</sup> session of the Commission.<sup>6</sup>

5. At its 42<sup>nd</sup> session of CCFH, the Committee agreed to review its risk analysis principles and procedures with a view to its simplification in line with Activity 2.2 of the Strategic Plan (2008-2013) and taking into account the recommendations in CL 2010/1-GP<sup>7</sup>. The Delegation of the European Union was requested to prepare a proposal in this regard for consideration by the next session of the Committee<sup>8</sup>.

## PROPOSED SIMPLIFICATION

6. The main part of the document clearly describes the risk analysis principles and procedures applied by CCFH following the classical sequence of steps and therefore fulfils the initial objectives set by the CAC and the recommendations from CCGP. The **Scope** clearly sets out the purpose of the document and is followed by the **Preliminary Risk Management Activities**, then the **Risk Assessment**, the **Risk Management** and the **Risk Communication**. Finally, section VI addresses the **Interaction between Risk Manager (CCFH) and Risk Assessor (JEMRA)**.

7. As regards the Annex, its content is not always directly related to risk analysis and is more about the process of work management of the Committee. Its purpose is to describe the process by which CCFH undertakes its work. The prioritisation process of new work is described in much detail going into every step of the procedure followed by the working group. Although this text contains valuable information, it does not contribute to any clarification on the risk analysis process followed by the Committee and is not appropriate for inclusion in the Procedural Manual.

8. There are in addition repetitions between the body of the document and the Annex and certain details should certainly be removed. For example, reference to the risk profile is made in paragraph 5 of the Annex, although it was already mentioned in paragraph 3 of the main document. Paragraphs 6 and 7 of the Annex deal with issues already detailed in the criteria for the establishment of work priorities.

9. On the basis of the rationale detailed above, it is proposed to delete the Annex and to retain only the text mentioned below<sup>9</sup>:

- the section **Prioritization of Proposals for New Work** and to transfer it to the body of the text as a new section between section I (Scope) and section II (Preliminary Risk management Activities);
- and part of the section **Obtaining Scientific Advice** and include it in section III Risk Assessment of the main document. Paragraph 12 of the Annex is not needed as this issue is already dealt with in section VI of the main document.

10. All these proposed changes appear in the Appendix to this discussion paper, in which the main document is reproduced. The parts transferred from the Annex appear **underlined characters**. Deletions

<sup>5</sup> ALINORM 10/33/33 para.11-16

<sup>6</sup> ALINORM 10/33/REP, para. 11

<sup>7</sup> ..." Taking into account the specificities of microbiological risk analysis, it appears that the main part of the document clearly describes the various components of risk analysis as applied in the area of food hygiene, including preliminary risk management activities and the establishment of a risk profile, and the steps of risk assessment applied by JEMRA.

As regards the Annex, the Committee may recall that a similar document was considered by the 23<sup>rd</sup> Session of the Committee (2006) (CX/GP 06/23/2 Part II) where some amendments were proposed and referred back to the CCFH (ALINORM 06/29/33, para. 45-57). One of the recommendations made at the time was that the Committee on Food Hygiene consider the development of a document explaining its policies in the application of risk analysis, as the document proposed included both elements related to decision making and interaction between risk assessors and risk managers.

The Annex includes detailed provisions on the process of work management in the Committee, which are not directly related to the risk analysis process. The Committee may wish to consider as a general issue whether such an Annex should be included in a document on risk analysis policies and whether this is consistent with the Working Principles. In other documents on risk analysis policies, there may be a few references to procedure or process issues, as mentioned in the relevant sections above, but in the CCFH document, these issues are discussed in considerable detail..."

<sup>8</sup> REP 11/FH para. 6

<sup>9</sup> It should be noted that Appendix V of ALINORM 07/30/13 contains all the information regarding the prioritisation process and the procedures followed by the ad-hoc working group. The Circular Letter that gets sent out requesting proposals for new work refers to the Appendix.

appear in ~~strike through characters~~. Changes made in the original text transferred from the Annex appear in **bold, underlined characters**.

11. This simplification would allow having a clearer text more focused on the risk analysis policy applied by CCFH and avoid the inclusion of details which are not relevant for the Procedural Manual.

**Appendix****RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE  
ON FOOD HYGIENE****(Section IV of the Procedural Manual)****I. SCOPE**

1. This document addresses the respective applications of risk analysis principles and procedures by the Codex Committee on Food Hygiene (CCFH) as the risk management body and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) as the risk assessment body. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* to which these principles are supplemental.

**II. PRIORITIZATION OF PROPOSALS FOR NEW WORK**

2. The Committee will prioritize its proposals for new work at each CCFH meeting, if required when appropriate. This will be usually carried out by the Committee after consideration of the recommendations from the an ad hoc Working Group. Theis ad hoc Working Group will consider the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the “Criteria for the Establishment of Work Priorities” and if necessary, additional criteria to be prepared by the Committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

**III. PRELIMINARY RISK MANAGEMENT ACTIVITIES**

3. The CCFH arranges to develop a risk profile for bringing forward newly proposed work. The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential microbiological risk management (MRM) options that have been identified by CCFH, if any, and the food safety policy context that will influence further possible actions. Scientific data may be commissioned from a range of sources so as to support a continuous science and risk based approach.

4. Members, who wish to make a request for inclusion of new item in the priority list of future work of CCFH, should prepare a project document in accordance with Part 2-1 of the Elaboration Procedure (Codex Procedural Manual) and provide a preliminary risk profile, based on the template in Annex 1 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)*. CCFH identifies the priority of all the new topics, submitted for its consideration, based on the *Criteria for the Establishment of Work Priorities (Codex Procedural Manual)*. The CCFH may also identify areas on which inputs from JEMRA are needed and make an appropriate request to JEMRA. Further details are provided in the Annex.

5. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessments and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.

6. When referring pathogen-commodity combinations to JEMRA, the CCFH may also refer a range of MRM options, with a view to obtaining JEMRA’s guidance on the attendant risks and the likely risk reductions associated with each option.

**IV. RISK ASSESSMENT**

7. CCFH commissions JEMRA, through FAO/WHO, as the body primarily responsible for performing international risk assessments upon which CCFH and the Codex Alimentarius Commission (CAC) will base MRM options. For matters, which cannot be addressed by JEMRA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.

8. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies (e.g. ICMSF). When undertaking such work, the Committee should follow the structured approach given in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development (CAC/GL 63-2007) and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

9. In seeking an international risk assessment to be conducted by FAO/WHO (e.g., through JEMRA), CCFH should consider and seek advice on whether:

i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)

ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.

iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

10. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favourably, the Committee will encourage its members to submit their relevant scientific data. 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).

11. FAO/WHO will ensure that the selection of experts and other procedures follow the principles and procedures in the *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition* and in accordance with the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).

12. JEMRA should:

- strive to base its risk assessments, on relevant data from different parts of the world, including that from developing countries;
- identify and communicate to CCFH in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will, as far as possible, identify potential risks to populations of potentially enhanced vulnerability, e.g., infants, immuno-compromised population;
- communicate to CCFH the magnitude and source of uncertainties in its risk assessments. When communicating this information, JEMRA should provide CCFH with a description of the methodology and procedures by which JEMRA estimated any uncertainty in its risk assessment;
- communicate to CCFH the basis for all assumptions and the level of uncertainty in risk assessment outcomes as well as key factors contributing to uncertainty in its risk assessment.

13. 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 FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/RCP 30-1999)*.

#### **IVV. RISK MANAGEMENT**

815. The MRM options recommended by the CCFH to the CAC should be based on the policies stated in the following paragraphs and shall take into account all relevant assumptions and uncertainties described by JEMRA.

916. Elaboration of ‘Guidelines’ or ‘Codes of Hygienic Practices’ could include Microbiological Criteria (MC) and/or provide enabling tools/procedures for countries to apply other MRM metrics (e.g., FSO, PO, PC), as outlined in Annex II of the MRM document (CAC/GL 63-2007), to address a food safety risk.

4017. In cases where JEMRA has performed a risk assessment and CCFH or the CAC determines that additional scientific guidance is necessary, CCFH or CAC may make a specific request to JEMRA to provide further scientific guidance necessary for deciding on an appropriate MRM option.

4118. CCFH decides, on a case-by-case basis, the need to elaborate ‘Guidelines’ or ‘Codes of Hygienic Practices’, and/or to establish an ‘MC’, or provide enabling tools/procedures for countries to apply other MRM metrics. In most cases, elaboration of a ‘Guideline’ or a ‘Code of Hygienic Practices’ is the preferred MRM option and should address food safety concerns in a diverse array of situations that prevail globally. It also provides the necessary flexibility to address/manage the risk to an acceptable level in the most efficient and appropriate manner. Also, for certain products that are intended for consumption by sensitive sub-populations (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immunocompromised persons, etc.), it may be necessary for the CCFH to establish MCs and/or provide enabling tools/procedures for countries to apply other MRM metrics.

4219. Where appropriate, other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, may also be considered by the CCFH, as described in the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Codex Procedural Manual). When establishing MRM options, CCFH shall clearly state when it applies any considerations based on other legitimate factors and specify its reasons for doing so.

4320. Wherever possible, CCFH should consider establishing MCs for those pathogen – food combinations for which JEMRA is able to provide a quantitative microbiological risk assessment. Recommendations by CCFH should be based on the outcomes of the risk assessment taking into account differences in regional and national food consumption patterns and dietary exposure. The applicable guidance provided in the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) shall be utilized by the CCFH for establishment of MCs.

4421. Where MCs are established, methods of analysis and sampling plans shall be provided, including validated reference methods.

#### **VVI. RISK COMMUNICATION**

4522. In accordance with the *Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCFH, in co-operation with JEMRA, should ensure that the risk analysis process is fully transparent and thoroughly documented and that the results are made available to the members in a timely manner. The CCFH recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities. To this end, the CCFH and JEMRA should utilise the guidance on interaction provided in paras 18 through 23.

4623. In order to ensure transparency of the risk assessment process in JEMRA, the CCFH may provide comments on the guidelines related to assessment procedures being drafted or published by JEMRA.

#### **VVII. INTERACTION BETWEEN RISK MANAGER (CCFH) AND RISK ASSESSOR (JEMRA)**

4824. The CCFH recognizes that an iterative process between risk managers and risk assessors is essential for adequate undertaking of any microbiological risk assessment and development of MRM options. In particular, a dialogue between the CCFH and JEMRA is desirable to thoroughly assess the feasibility of the

risk assessment, to assure that the risk assessment policy is clear, and to ensure that the risk management questions posed by the CCFH are appropriate.

~~17~~25. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees, other FAO/WHO expert consultations and/or other specialized international scientific bodies, these should be included into the iterative process.

~~19~~26. It is essential that communications between CCFH and JEMRA are timely and effective.

~~20~~27. CCFH is likely to receive questions from JEMRA relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the MRM options to be considered and key assumptions to be made regarding the risk assessment. Likewise, the CCFH may pose questions to JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop the MRM options.

~~22~~28. CCFH may recommend to the CAC to discontinue or modify work on an MRM option if the iterative process demonstrates that: (a) completion of an adequate risk assessment is not feasible; or (b) it is not possible to provide appropriate MRM options.

~~23~~29. CCFH and JEMRA should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members.