

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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Agenda Item 10b

**CX/FH 09/41/11-Rev
October 2009**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty first Session

Coronado Hotel, San Diego, United States of America

PROPOSED DRAFT RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE

(Prepared by India with the help of Australia, Brazil, Canada, the European Commission, Finland, France, Germany, Japan, Peru, Philippines, Thailand, UK, USA, FAO, WHO and IDF)

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Risk Analysis Principles (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*) to: Mrs Barbara McNiff, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, EE.UU., FAX +1-202-690-4719, or email: Barbara.McNiff@fsis.usda.gov with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 by **20 October 2009**.

Introduction

1. The 26th Session of the CAC, June-July 2003, adopted the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. It requested all Codex Committees to develop or complete specific guidelines on risk analysis in their respective areas for inclusion in the Procedural Manual and noted that these texts would be submitted to the CCGP in order to ensure coordination of work and consistency with overarching Working Principles (ALINORM 03/41, Paras 146 and 147).

Background

2. The 36th Session of the CCFH, March-April 2004, while considering the Principles and Guidelines for the Conduct of Microbiological Risk Management, noted the request of the 26th Session of the CAC that relevant Committees develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual. The Committee also reported the steps taken by it to the Commission and sought its advice whether these were consistent with the Commission's expectations (ALINORM 04/27/13, Paras 63-74).

3. The 27th Session of the Commission held in June-July 2004, agreed to initiate the preparation of a new Strategic Plan for the period 2008 - 2013. The Commission decided to request each relevant Committee, when developing or completing specific guidelines on risk analysis, to review and document the mechanism it uses to identify and prioritize proposals for new work, particularly, in light of the need for and availability of scientific advice (ALINORM 04/27/41, Paras 123 and 124).

4. The CCFH, at its 37th Session in March 2005, noted that the Commission endorsed the view that the past and ongoing work by the Committee on the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999) and the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management, addressing issues relevant to both member governments and to the Codex, was consistent with the Commission's expectations (ALINORM 05/28/13, Para 12).

5. The CCFH, at its 38th Session in November 2006, noted that the 23rd CCGP, April 2006 had considered and made amendments to the document on the proposed process by which the Codex Committee on Food Hygiene will undertake its work. The Committee agreed with these amendments and to utilize the amended document for the management of its work. The Committee also noted the recommendation of the CCGP to develop the document on the application of risk analysis policies applied by the Food Hygiene Committee, which might include interaction between the CCFH and JEMRA for possible inclusion in the Procedural Manual. The Committee agreed to this suggestion of the CCGP and referred the proposal for the work on the development of the CCFH Risk Analysis Policies to the CCFH Working Group on Priorities for its consideration (ALINORM 07/30/13, Paras 15, 17 and Appendix V).

6. The *ad-hoc* working group for the establishment of CCFH work priorities that met prior to the 39th Session of the CCFH, October-November 2007, noted, with regard to the scope and nature of the proposed CCFH document, that the CCFH required developing a policy document to elaborate how the risk analysis principles were to be applied by the Committee. Hence, the document would be basically referencing the already adopted CCFH texts related to its working procedures and risk analysis principles and would include an iterative process (Attachment 1 to the document CX/FH 07/39/09) between the CCFH and the FAO/WHO for obtaining scientific advice. It would also have some additional text based on experience of the CCFH with the risk analysis paradigm (CRD1 of the 39th Session of the CCFH).

7. At the 39th Session of the CCFH, Oct.-Nov. 2007, the Codex Secretariat recalled the request from the Commission for the Committee to develop a Risk Analysis Policy document to guide its work as part of the Codex Strategic Plan. 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 (ALINORM 08/31/13, Paras 161 and 162).

8. The Codex Strategic Plan 2008-2013 was adopted by the Commission in its 30th Session in 2007. The Activity 2, namely, 'Review risk analysis principles developed by relevant Codex Committees', under Goal 2 -- 'Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis' of the Strategic Plan, required that the Codex Committee on Food Hygiene (CCFH) develop its risk analysis principles.

Documents Developed by Other Committees

9. All the other relevant Codex Committees, except the CCFH have elaborated the relevant documents as required by the Activity No. 2.2 of the Strategic Plan. These documents have been included in the Codex Procedural Manual (18th Edition) and are listed below:

- Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods
- Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminant and Toxins in Foods or Food Groups
- Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues
- Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods
- Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods
- Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses

Documents Developed by the CCFH

11. The following documents elaborated by the CCFH are related to its working procedures and application of risk analysis in its working:

- Process by Which the Codex Committee on Food Hygiene will Undertake its Work (ALINORM 07/30/13, Appendix V)
- Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL-21, 1997)
- Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999)
- Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63, 2007)

12. It will be appropriate and helpful to provide references to the guidance provided in these documents in the proposed risk analysis policy document of the CCFH.

Proposed Contents of the CCFH Document

13. The documents developed by the other relevant Committees differ in their presentation and contents with respect to the inclusion of the risk analysis 'Principles' and 'Policies'. These documents are, however, useful in providing guidance to the CCFH Policy document.

14. In relation to the CCFH, the *ad-hoc* working group for the establishment of CCFH work priorities that met prior to the 39th Session of the CCFH in 2007 was of the view that the document would be basically referencing the already adopted CCFH texts related to its working procedures and risk analysis principles and would include an iterative process (Attachment 1 to the document CX/FH 07/39/09) between the CCFH and the FAO/WHO for obtaining scientific advice. It would also have some additional text based on experience of the CCFH with the risk analysis paradigm (CRD-1 of the 39th Session of the CCFH).

15. Accordingly, a draft on the Risk Analysis Policy of the CCFH prepared by India was circulated by the Codex Secretariat to the Codex members for and Observers for comments by 29th May 2009 and its further development. Comments were received from some members of the e-Working Group. The revised draft was circulated by India to the e-Working Group members on 8th September 2009 for comments by 15th September. Taking into consideration the comments received, the document has been further revised and the revised version is attached as Appendix - 1.

Request to the Committee

16. The Codex Committee on Food Hygiene is invited to consider the proposed draft of "Proposed Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene" presented in Appendix - 1.

APPENDIX I

PROPOSED DRAFT RISK ANALYSIS PRINCIPLES AND PROCEDURES**APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE**

[for inclusion in Section VI of the 18th Edition 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. It is, however, recognized that, in certain instances, the CCFH may request scientific advice from other FAO/WHO expert consultations and/or other specialized international scientific bodies (e.g. ICMSF), as approved by the Commission. When this is the case, the provisions in this document applicable to JEMRA apply, as appropriate, to other FAO/WHO expert consultations and other specialized international scientific bodies. 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. RISK ASSESSMENT

2. The JEMRA is primarily responsible for performing international risk assessments upon which CCFH and the Codex Alimentarius Commission (CAC) will base microbiological risk management (MRM) options. However, in certain instances, the CCFH may request such scientific advice from other FAO/WHO expert consultations and/or other specialized international scientific bodies, as approved by the CAC.
3. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessment and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.
4. 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 MRM options that have been identified to date, when any, and the food safety policy context that will influence further possible actions.
5. JEMRA provides CCFH with risk assessments that typically include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFH's risk-management decisions. For this, the JEMRA shall utilize the guidance provided in the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999). JEMRA's recommendations should be strictly limited to its risk assessment findings.
6. JEMRA will ensure that there is a public call for data pertinent to its risk assessments.
7. JEMRA should strive to base its recommendations, and hence the risk assessments, on global data, including that from developing countries.
8. JEMRA should 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., children.
9. JEMRA should communicate to CCFH the magnitude and source of uncertainties in its risk assessments. When communicating this information, JEMRA should provide CCFH a description of the methodology and procedures by which JEMRA estimated any uncertainty assessments in its risk assessment.
10. JEMRA should communicate to CCFH the basis for all assumptions used in its risk assessment.

III. RISK MANAGEMENT

11. CCFH is responsible for developing proposals for new work for the development of MRM options

for adoption by the CAC. For this, the CCFH shall utilize the guidance provided in the *Process by which the Codex Committee on Food Hygiene will Undertake its Work (ALINORM 07/30/13, Appendix V)*, which is annexed to this document; and the *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63, 2007)*.

- 12 Members, who wish to make a request for inclusion of new topics 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, 18th Edition, p. 30) and provide a preliminary risk profile, based on the template in the 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, 18th Edition, p. 42)*. The CCFH also identifies areas on which inputs from JEMRA are required and refers them, according to the identified priorities, to JEMRA for risk assessment.
- 13 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 the relevant uncertainties described by JEMRA.
- 14 The main MRM options exercised by the CCFH are elaboration of 'Guidelines' or 'Codes of Hygienic Practices', which could include Microbiological Criteria (MC) and/or MRM metrics (e.g., FSO, PO, PC) as outlined in Annex II of the MRM document (CAC/GL 63) to address a food safety risk..
- 15 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 an appropriate MRM option.
- 16 CCFH decides, on a case-by-case basis, the need to elaborate 'Guidelines' or 'Codes of Hygienic Practices', and/or establish a 'MC', or other MRM metrics as its MRM option(s). 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-population (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immuno-compromised persons, etc.), it should be necessary for the CCFH to establish MCs. In cases, where the tolerance for risk through foods is extremely low, it might be appropriate for the CCFH to establish MRM metrics.
- 17 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, 18th Edition,). 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.
- 18 CCFH shall consider establishing MC only for those pathogens for which JEMRA is able to provide appropriate scientific analysis & advice, and, where sufficient data are available, a risk analysis appropriate to the foodstuff and its use. CCFH shall base its recommendations on the dose response model and exposure assessment including the consumption patterns on a global basis when appropriate data are available. The probability of exposure to certain dose(s) should take into account the normally used consumption pattern including serving size data and preparation practices provided by the members. 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.
- 19 Methods of analysis and sampling plans should be provided, where relevant, and include validated reference methods provided these methods are transparent and accessible. If no reference methods of analysis are available for verifying compliance to MCs or other metrics for a specific pathogen commodity combination, no MC or MRM metrics will be established by CCFH.
- 20 When referring pathogen-commodity combinations to JEMRA, the CCFH shall provide background information and clearly specify the reasons for the request through the elaboration of

risk profile (Annex I of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL-63,2007) when pathogen-commodity combinations are identified for evaluation.

- 21 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 COMMUNICATION

- 22 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, shall 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 25 through 30.
- 23 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.
- 24 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.

V. INTERACTION BETWEEN RISK MANAGER (CCFH) AND RISK ASSESSOR (JEMRA)¹

- 25 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 risk assessment policy is clear, and to ensure that the risk management questions posed by the CCFH are appropriate.
- 26 If JEMRA agrees that the requested risk assessment proposed is feasible and will be undertaken, a series of planned interactions between the JEMRA and the CCFH should be scheduled to assure effective interaction.
- 27 It is essential that communications between these entities are timely and effective.
- 28 The 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 and/or understand the MRM options selected.
- 29 The 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.
- 30 The 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.

¹ The CCFH, at its 38th Session, 2008, had agreed to delete the text on the proposed iterative process between the CCFH and JEMRA from its document 'Proposed Process by Which the Codex Committee on Food Hygiene will Undertake its Work' with the understanding that the text, with some portions in square brackets, would be considered for incorporation in the risk analysis policies document (ALINORM 07/30/13, para. 17). Accordingly, the text (Appendix – 1 to the document CX/FH 07/39/09) has been included here.

PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK

Purpose

1. The following guidelines are established to assist the CCFH to:

- Identify, prioritize and efficiently carry out its work; and
- Interact with FAO/WHO and their scientific bodies as the need arises.

Scope

2. These guidelines apply to all work undertaken by the CCFH and encompass: guidelines and procedures for proposing new work; criteria and procedures for considering the priorities for proposed and existing work; procedures for implementing new work; and a process by which CCFH will obtain scientific advice from FAO/WHO.

Process for Considering Proposals for New Work

3. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities (“*ad hoc* Working Group”) at each Session, in accordance with the Guidelines on Physical Working Groups.

4. The Codex Committee on Food Hygiene will, normally, employ the following process for undertaking new work.

- i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.
- ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the *ad hoc* Working Group as well as the CCFH Host government and Codex Secretariats.
- iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.
- iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.

If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the ‘Criteria for the Establishment of Work Priorities’¹. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be “denied” or “returned for revision,” a justification for this recommendation will be provided.

- v. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a

¹ Codex Alimentarius Commission, *Procedural Manual*, 16th Edition

project document², which may include amendments agreed upon by the Committee, will be prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work.

Proposals for New Work

5. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile³, as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

6. The proposals for new work will typically address a food hygiene issue of public health significance. It should describe in as much detail as possible, the scope and impact of the issue and the extent to which it impacts on international trade.

7. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees, provided it is consistent with the mandate of CCFH;
- facilitate risk analysis activities; or
- establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/or improve consistency with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

Prioritization of Proposals for New Work

8. The Committee will prioritize its proposals for new work at each CCFH meeting, if required. This will be carried out by the Committee after consideration of the recommendations from the *ad hoc* Working Group. The *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.

Obtaining Scientific Advice

9. 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 *Codex Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development and the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*⁴.

10. 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.)

² The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*, 16th Edition.

³ Definition of a risk profile is “the description of the food safety problem and its context” (Codex Alimentarius Commission, *Procedural Manual*, 16th Edition). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

⁴ Codex Alimentarius Commission, *Procedural Manual*, 16th edition.

- 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.

11. 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).

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

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 030-1999).