

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 2

CX/GP 05/22/2

Add.1

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-second Session
Paris, France, 11 – 15 April 2005**

**MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION
AND OTHER CODEX COMMITTEES**

“The Management of the Work of the Codex Committee on Food Hygiene”

1. The 37th Session of the Codex Committee on Food Hygiene recalled that its 36th Session had agreed to consolidate into a single discussion paper the following discussion papers on the Management of the work of the Committee:

- *Proposed draft Process by which the Committee on Food Hygiene could undertake its work in Microbiological Risk Assessment/Risk Managements (CX/FH 04/5);*
- *Development of Process, Procedures and Criteria to establish Priorities for the Work of the Codex Committee on Food Hygiene (CX/FH 04/5, Add.2);*
- *The Development of Options for a Cross-Committee Interaction Process (CX/FH 04/5, Add.3).*

2. At that Session, the Committee had agreed to attach the consolidated document to its report and to circulate it for comments. It further agreed that a Working Group led by the United States would revise the document based on the discussions and the comments submitted at the 36th session and those received in response to the Circular Letter for comments for further discussion at its present session.

3. The 37th Session of the Committee considered the revised documents and agreed to forward the amended “Proposed Process by which the Codex Committee on Food Hygiene will undertake its work” (see Appendix) to the Codex Committee on General Principle for its advice on its consistency with established procedures in Codex.

4. The Committee decided to immediately begin to use this Process on an interim basis for the management of its work. The Committee agreed to convene an *ad hoc* Working Group, to be chaired by Australia, before its next session to develop recommendations for consideration by the Committee on the acceptance, revision and/or rejection of proposals for new work (ALINORM 05/28/13 paras 18-34).

5. The Codex Committee on General Principles is invited to provide guidance to the Codex Committee on Food Hygiene on the basis of the request stated in para. 3 above.

Appendix

MANAGEMENT OF THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE

The Proposed 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 other Codex Committees, Task Forces, and 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; the approach to interaction of CCFH with other Codex Committees and/or Task Forces on items of mutual interest; 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 will establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities ("*ad hoc* Working Group") at each Session.

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
 - ii. New work and/or revision of an existing standard may be proposed by the Committee on its own initiative, by another Codex subsidiary body upon referral to CCFH or by an individual member or members.
 - iii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the *ad hoc* Working Group Chair by the Host Country and Codex Secretariats.
 - iv. The Chair 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.
 - v. The *ad hoc* Working Group will meet on the day before the opening 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 recommendation 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.

- vi. 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 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. As specified in the *Codex Procedural Manual*, work undertaken by the CCFH should fall within its Terms of Reference, should be consistent with the strategic plan and the general procedures established by the Codex Alimentarius Commission, and should meet the *Codex Criteria for the Establishment of Work Priorities*.

6. The proposals for new work shall be in written form and consistent with, and include the specified elements of the project document³ required for approval of new work by the Codex Alimentarius Commission. The proposals for new work will include a Risk Profile⁴, 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).

7. 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.

8. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees;
- 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, Rev. 4-2003).

¹ *Codex Procedural Manual*, 14th Edition.

² The elements of a project document are described in the *Codex Procedural Manual*, 14th Edition.

³ Specifications for project document as approved by CAC at its 27th Session. *Codex Procedural Manual*, 14th Editions.

⁴ Definition of a risk profile is “the description of the food safety problem and its context” (*Codex Procedural Manual*, 14th Edition). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

Prioritization of Proposals for New Work

9. The Committee will prioritize its proposals for new work at each CCFH meeting. 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. The recommendations will include a prioritization of proposals for new work that meet the criteria specified by the CAC⁵ and if necessary, additional criteria specified in a Terms of Reference the *ad hoc* Working Group to be prepared by the Committee to. 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 proposal for new work needed to control an urgent public health problem.

10. The *Ad hoc* Working Group will also assess and provide recommendations to CCFH on the need for cross-committee interactions (see below).

11. If the proposed new work will benefit from the acquisition of additional expert scientific advice such as an international risk assessment, the need for obtaining the advice from FAO/WHO should also be considered in prioritizing work (see below).

Process for Commencement of Proposals for New Work within CCFH

12. Upon approval of the proposal for new work and/or revision of an existing standard by the CAC, the work will be undertaken through the Codex Step Procedure as provided for in the Codex *Procedural Manual* “*Procedures for the Elaboration of Codex Standards and Related Texts*”.

13. An electronic or physical working group may be established to assist the Committee to undertake the work. Working groups established by the Committee will follow the criteria established by CAC.⁶

14. As necessary and appropriate, CCFH work will request a risk assessment or other expert scientific advice from FAO/WHO using the procedure outlined below.

Obtaining Scientific Advice

15. 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, etc.), 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). The Committee will also keep in mind the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*⁷.

16. 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.

⁵ ALINORM 05/28/33; Appendix V.

⁶ Criteria developed for adoption by the Commission. See report of the 21st CCGP, ALINORM 05/28/33, Appendices V and VI.

⁷ Codex *Procedural Manual*, 14th edition.

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

17. 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 undertaken⁸. While CCFH establishes its own priorities it is recognized that any requests to FAO/WHO for scientific advice including risk assessments will be subject to FAO/WHO work prioritization criteria as agreed at the 55th session of CCEXEC⁹. 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 favorably, 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).

18. 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). The iterative process is described in Annex I.

19. 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 at Committee session or working group, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

20. 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 020-1999).

Providing for Cross-Committee Interaction to Conduct CCFH Work

21. It is noted that there are already some mechanisms in place to facilitate cross-committee interactions through the regular agenda item, Matters Referred, from the CAC and other Codex Committees. It is also noted that the Codex Committee structure and mandates of Codex Committees and task forces is being subjected to external review. The outcome of this review may affect the interaction of CCFH with other Codex Committees. The need for guidance to facilitate interaction between CCFH and other committees will be further considered after the CAC responds to this external review.

⁸ Codex *Procedural Manual*, 14th Edition, p. 46 (definition of risk assessment policy) and pp. 102-104 (working principles relating to risk assessment policy).

⁹ ALINORM 05/28/3 (para 75).

Annex I**ITERATIVE PROCESS BETWEEN THE CODEX COMMITTEE ON FOOD HYGIENE AND
FAO/WHO FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT**

The Codex Committee on Food Hygiene 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, to assure that risk assessment policy are clear, and to ensure that the risk management questions posed by the Committee are appropriate. If FAO/WHO agrees that the requested risk assessment proposed in the Risk Profile is feasible and will be undertaken, a series of planned interactions between the FAO/WHO JEMRA and the Committee or its Working Group established to develop the risk management guidance document should be scheduled to assure effective interaction. 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.

It is essential that communications between these entities are timely and effective. 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.

The Committee and/or its liaison (i.e., the Working Group) is likely to receive questions from FAO/WHO or the designated risk assessment body (e.g., 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 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. Likewise, the Committee and/or its liaison (i.e., the Working Group) may pose questions to FAO/WHO or their designation (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. Timely, appropriate responses are needed for these interactions.

The Committee may elect to discontinue or modify work on a risk assessment if the iterative process demonstrates that: 1) completion of an adequate risk assessment is not feasible; or 2) it is not possible to provide appropriate risk management options. However, FAO/WHO may decide to continue the work if it is considered necessary to meet the needs of their member countries.