

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 2 b)

CX/GP 06/23/2 Part II

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-third Session
Paris, France, 10 – 14 April 2006**

MATTERS REFERRED TO THE COMMITTEE

MATTERS ARISING FROM THE LAST SESSION OF THE COMMITTEE ON GENERAL PRINCIPLES: MANAGEMENT OF THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE

The 22nd Session of the Committee on General Principles considered the “Proposed Process by which the Codex Committee on Food Hygiene will undertake its work” submitted by the 37th Session of the Committee on Food Hygiene for its advice on its consistency with established procedures in Codex.

The Committee on General Principles noted that the text actually contained two elements, one addressing the process for prioritization of work, which basically fell under the responsibility of the Committee on Food Hygiene as long as the proposed mechanism adhered to the overall Codex procedure, and the other concerning the interaction between that Committee and scientific bodies conducting risk assessments. It was suggested that the latter element could be considered a useful documentation of the risk analysis process followed by the Committee on Food Hygiene, and could further be developed for inclusion in the Procedural Manual in the future.

Following a general discussion on the document, the Committee on General Principles agreed to consider this matter again at its next session and agreed to request legal advice from the Legal Counsels of FAO and WHO on the consistency of the texts referred from the Committee on Food Hygiene with Codex procedures (ALINORM 05/28/33A, paras. 25-30).

The Committee is invited to consider the comments made by the Secretariat and the Legal Counsels of FAO and WHO concerning the texts proposed by the Committee on Food Hygiene. The texts are presented with proposed amendments highlighted in **Appendix 1**.

General aspects

When procedures, criteria or other recommendations are established for a Codex Committee, they should mainly focus on the elements that refer specifically to that Committee and should avoid repetition of the general procedures and recommendations applicable throughout Codex. It is therefore proposed to simplify some sections of both texts in order to avoid repetition of provisions that already apply to all Committees, including the Committee on Food Hygiene.

The provision allowing a Working Group to interact directly with risk assessors of FAO/WHO (JEMRA) on behalf of the Committee appears to be in contradiction with the provisions of the Procedural Manual applicable to working groups and to risk analysis. The *Guidelines on Physical Working Groups* clearly state that “*No decision on behalf of the Committee, nor vote, either on point of substance or of procedure shall take place in working groups*”, and therefore Working Groups cannot systematically take a decision to act independently on behalf of the Committee and to provide their views directly to FAO and WHO. Any

Working Group should refer its proposals to the Committee for consideration in the plenary session, in conformity with the provisions of the *Guidelines*.

As regards risk analysis, the *Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius* specify that “Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).”

The interaction is clearly between Codex Committees and the expert committees, in the present case between the Committee on Food Hygiene and JEMRA and throughout the text risk managers are understood as Codex Committee and Task Forces. There is no reference to a delegation of the responsibility of the Committee as regards risk management to a working group or to similar arrangements.

From a more general point of view, the delegation of responsibility to a Working Group for the purposes of risk management would also impair the transparency of the process of interaction between risk assessors and risk managers. Working Groups may be established to discuss any matter of relevance to the Committee and to facilitate its work, but in any case they should always report to the Committee concerned.

In view of the above, it is proposed to delete the reference to a Working Group in Annex I of the document.

Purpose and Scope

The main purpose of the document is to facilitate prioritization of work and interaction with risk assessors. It may be questioned whether the document should also apply to other aspects at this stage, and especially interaction with other committees or task forces. The same comment applies to paragraph 21.

The Committee on General Principles may wish to consider whether current provisions in the Procedural Manual as regards the relations or interaction between subsidiary bodies are sufficient or whether the development of additional provisions is necessary. If there is a need for clarification, it would be preferable to address it throughout Codex rather than developing specific provisions only in the case of the Committee on Food Hygiene.

Process for Considering Proposals for New Work

The establishment of a working group may not be necessary in all cases or may not be feasible for practical reasons, and its timing may not always be the same. Similar working groups in other committees are regularly convened but the decision is taken at each session and is not an obligation for the Committee.

The document also assumes that proposals for new work will be submitted on a continuing basis. However there may be sessions where no new proposals are made and there may be no need for further prioritisation. Some changes have therefore been proposed throughout the section in order to allow some flexibility in the organization of the Committee’s work on a case by case basis.

Proposals for new Work, Prioritisation of Proposals for new Work , and Process for Commencement of Proposals for New Work within CCFH

As mentioned in the general comments above, it is proposed to simplify these sections and to retain only specific recommendations applying to food hygiene.

Providing for Cross-Committee Interaction to Conduct CCFH Work

In addition to the general considerations on the Purpose and Scope (see above), this paragraph, presented as a comment, would not appear as such in the final version and it is therefore proposed to delete it.

Obtaining Scientific Advice and Annex 1

As mentioned in the general comments, the delegation of responsibility to a working group in the interaction with FAO/WHO is not consistent with the current provisions of the Procedural Manual and would detract from the overall transparency of the process, and it is proposed to amend the text accordingly.

The remaining provisions in these sections are intended to clarify the interaction process and do not raise substantial issues of principle. However, in order to simplify the text, these two sections might be combined and simplified in order to retain only essential elements and to avoid repetition or general statements that

appear in the *Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius*. Some of these sections are placed in square brackets for further consideration.

Next Step

The Committee on General Principles may wish to recommend the following to the Committee on Food Hygiene:

- (1) The sections on the “Process for Considering Proposals for New Work”, “Proposals for New Work” and “Prioritisation of Proposals for New Work” be finalised by the CCFH, in the light of the comments and recommendations made by the present session of the CCGP. The final text will be published in the report of CCFH and would serve as the document describing working arrangements internal to CCFH;
- (2) The section on “Obtaining Scientific Advice” and Annex 1 be reviewed by the CCFH, in the light of the comments and recommendations made by the present session of the CCGP. The document, with the addition of further elements as appropriate, would constitute specific guidelines on risk analysis, for inclusion in the Procedural Manual. The decision of the 26th Session of the Commission (ALINORM 03/41, para. 147) should be followed in guiding further development of the document.

APPENDIX 1

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~~ **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. ~~[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 **Host of the ad hoc Working Group as well as the CCFH Chair by the Host government Country** and Codex Secretariats.
- iv. The **Chair 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.
- v. The *ad hoc* Working Group will meet ~~as decided by the Committee, normally on the day before prior to the opening 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

¹ Codex Procedural Manual, 15th Edition.

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. In addition to the provisions applying to proposals for new work in the Procedural Manual, 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 should 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, **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, Rev. 4-2003).

Prioritization of Proposals for New Work

~~9. 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. The recommendations will include a prioritization of proposals for new work that meet the in accordance with the “Criteria for the Establishment of Work Priorities” criteria specified by the CAC 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).~~

² The elements of a project document are described in the Codex Procedural Manual, 15th Edition.

³ Specifications for project document as approved by CAC at its 27th Session. Codex Procedural Manual, 15th 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.

~~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.⁵~~

~~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), 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 and the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius⁶.~~

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.
- 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 undertaken. ~~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 CCEXEC. 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

⁵ Criteria developed for adoption by the Commission. See report of the 21st CCGP, ALINORM 05/28/33, Appendices V and VI.

⁶ Codex Procedural Manual, 15th edition.

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 ~~to the Committee 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.~~

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.