

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3

**CX/FH 05/37/03
December 2004**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-seventh Session

Buenos Aires, Argentina, 14 - 19 March 2005

DISCUSSION PAPER ON THE MANAGEMENT OF THE WORK OF THE COMMITTEE

Prepared by the United States in collaboration with Australia, Canada, Finland, India, Ireland, France, Germany, Japan, New Zealand, the Netherlands, Norway, Sweden, the United Kingdom, the Commission of the European Community, Food and Agriculture Organization of the United Nations, and World Health Organization

Governments and interested international organizations are invited to submit comments on the attached document (see Appendix) **to:** Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to:** Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 February 2005.**

BACKGROUND

During the 36th Session of the Codex Committee on Food Hygiene (CCFH), it was 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 Management* (Agenda Item 5(a), CX/FH 04/5);
- *Development Of Process, Procedures And Criteria To Establish Priorities For The Work Of The Codex Committee On Food Hygiene* (Agenda Item 5(b), CX/FH 04/5-Add.2);
- *The Development Of Options For A Cross-Committee Interaction Process* (Agenda Item 5(c), CX/FH 04/5, Add.3).

At the above Session, the Committee suggested that the consolidated document be further simplified, shortened, and focused on process. It agreed to attach the consolidated version of the document to the report the without the Appendix on Risk Profile and to circulate it for comments. The Appendix was transferred for inclusion in the CCFH document, "*Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*." A new Working Group was established to assist in the revision of the document.

REVISED DOCUMENT

The Working Group agreed to conduct its work through electronic communication to revise the document based on guidance from CCFH at its 36th meeting and subsequent country comments. In revising the document, the Working Group focused on process and removed language related to risk management guidance documents. The process flow chart was edited to be more consistent the described process and a decision chart added to assist with prioritization.

While significant progress was made by the working group to improve the document, additional issues need clarification. These issues are listed below.

- 1) How will the Working Group for the Establishment of CCFH Work Priorities be constituted?
Have the appropriate checks and balances been established to ensure that this working group does not inappropriately or non-transparently influence the decision taking process within CCFH?
- 2) Are the weights suggested for selection and priority setting criteria appropriate and complete?
- 3) How should the sections on cross-committee interaction and Annex II, the iterative process with JEMRA, be revised to better take into account Codex structure and mode of operation?

RECOMMENDATION

The Working Group considers that the Discussion Paper on the Management of the Work of the Committee has significantly progressed (see Appendix). Further discussion of the document and issues noted above will occur at a Working Group to be held immediately prior to the 37th CCFH session so that progress on the document can be achieved at the plenary session.

APPENDIX**DISCUSSION PAPER ON THE MANAGEMENT OF THE WORK OF THE COMMITTEE****BACKGROUND**

The Codex Committee on Food Hygiene (CCFH) is moving towards a broad risk management-based approach to developing recommendations on protecting the health of the consumers and ensuring fair practices in the food trade. This broad risk-management approach may employ microbiological risk assessment and may utilize a spectrum of risk management or risk communication work products including guidance documents, codes of hygienic practice, food safety objectives and microbiological criteria.

The Codex Alimentarius Commission recognized this change in the Committee's operation by adopting, at its 24th Session, two additional Terms of Reference for the Committee. Specifically, these are:

- To suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessor.
- To consider microbiological risk management matters in relation to food hygiene and in relation to the microbiological risk assessment activities of Food and Agriculture Organization of the United Nations (FAO), and World Health Organization (WHO).

The Committee recognized that the process of initiating work, preparing a microbiological risk assessment and developing a risk management strategy is a complex process, involving CCFH, specific members, and FAO/WHO and their scientific bodies e.g., the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). The Committee also recognized that a structured, yet flexible process was needed to initiate and carry out this work in a timely, orderly and complete fashion. The Committee, at its 34th Session, considered a Document (CX/FH 01/5 – Add.2) on a “*Proposal for a Process by which the Codex Committee on Food Hygiene Could Undertake Its’ Work in Microbiological Risk Assessment/Risk Management*” originally submitted by the United States as a Conference Room Document at the 33rd Session of CCFH.

The Committee agreed that establishing a process in regards to undertaking its work on microbiological risk management was beneficial and invited the United States to prepare a Discussion Paper on the subject for the Committee's consideration at its 35th Session.

During the 35th Session, CCFH requested the United States to revise the described process concerning work related to risk management so that it was simple, short, and flexible as possible. It was agreed that the revised document should be circulated for further consideration and pending the outcome of the discussions be considered for inclusion in the Codex Alimentarius Procedural Manual. A drafting group consisting of the United States of America in collaboration with Australia, Canada, India, Ireland, France, Germany, Japan, New Zealand, the Netherlands, Sweden, the United Kingdom, the Commission of the European Community, Food and Agriculture Organization of the United Nations, and World Health Organization was established to assist in the revision of the document.

During the 35th Session, CCFH also concluded that because of increasing work load there was a need to develop a transparent procedure with established criteria for prioritizing its work. Furthermore, since much of the work undertaken by CCFH impacts other Codex committees, the Committee also recognized that its efficiency would be improved through effective communications with other Codex committees. Two working groups were established to develop discussion papers to address these needs: “*Discussion Paper on the Development of Process, Procedures, and Criteria to Establish Priorities for the Work of the Codex Committee on Food Hygiene*” which was led by New Zealand with the assistance of Australia, Austria, Brazil, Canada, Denmark, Finland, France, Japan, Malaysia, Norway, UK and the United States, and “*Discussion Paper on the Development of Options for Cross-Committee Communication Process*” led by Australia with the assistance of France, Norway, New Zealand, the United States and the European Commission.

From discussions among the three working groups, it was evident that there is substantial overlap in areas being addressed, and that it would be more effective to consolidate the three documents. During the opening session of the 36th Session of the CCFH, the leads of the three working groups recommended to the Committee the consolidation of the following work items:

- *Proposed Draft Process By Which The Committee On Food Hygiene Could Undertake Its Work In Microbiological Risk Assessment/Risk Management.* (Agenda Item 5(a), CX/FH 04/5).
- *Development Of Process, Procedures And Criteria To Establish Priorities For The Work Of The Codex Committee On Food Hygiene* (Agenda Item 5(b), CX/FH 04/5-Add.2. (Discussion Paper)
- *The Development Of Options For A Cross-Committee Interaction Process* (Agenda Item 5(c), CX/FH 04/5, Add.3). (Discussion Paper)

In recommending to the Committee the consolidation of the three documents, the three working groups were cognizant of the “Codex Strategic Framework 2003-2007” and the activities of the Codex Committee on General Principles (CCGP) related to their review of the Codex *Procedural Manual* in response to Codex Evaluation. In particular, the working groups considered the draft changes related to “Criteria for the Establishment of Work Priorities” and the draft text on guidelines for the establishment and functioning of work groups, both physical and electronic. The following document is intended to be consistent with and further elucidate how CCFH will implement and augment the general approach being developed by CCGP.

During the 36th session, the Committee recommended that the consolidated document be further simplified, shortened, and focused on process. The consolidated document (without the Appendix on Risk Profile) was circulated for comments. A working group consisting of the United States of America in collaboration with Australia, Canada, Finland, India, Ireland, France, Germany, Japan, New Zealand, the Netherlands, Norway, Sweden, the United Kingdom, the Commission of the European Community, Food and Agriculture Organization of the United Nations, and World Health Organization was established to assist in the revision of the document.

The Process By Which the Codex Committee on Food Hygiene Will Undertake Its Work

Purpose

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

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; means for fostering and guiding the interaction of CCFH with other Codex committees and/or task forces on items of mutual interest, e.g., standards for commodities; and a process by which CCFH will interact with FAO/WHO and their scientific bodies to acquire scientific advice or conduct a microbiological risk assessment.

Process for Considering New Work

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

1. A proposal for new work and/or revision of an existing standard shall be developed. 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, by an individual member or members, or by a recognized international organization.

The proposal shall be in written form and consistent with, and include the specified elements of the project document¹ required for approval of new work by the Codex Alimentarius Commission. Preferably the proposal would be submitted in time to be included in the formal agenda of the CCFH meeting at which the nominator wishes to have the proposal considered.

¹ Specifications for project document as approved by CAC at its 27th Session. Codex Procedural Manual, 14th Editions, p. 20.

To facilitate decision-making, when undertaking new work in the management of foodborne microbial hazards, the proposal should include a risk profile. A risk profile² is an abbreviated discussion paper that lays out the key elements of a food hygiene issue of public health significance in order to facilitate decision-making on the part of the Committee in relation to the need, feasibility, and scope of the newly proposed work.

The proposal should indicate the specific nature or outcome of the new work that is being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

2. The proposal, including, as appropriate, the Risk Profile and the scientific issues underlying the new work, will be reviewed by the Committee. To facilitate this process, CCFH will establish an [*Ad hoc*] “Working Group for the Establishment of CCFH Work Priorities,” before its session, as appropriate (see below) to review the proposals and provide recommendations to the Committee regarding the proposals’ suitability, feasibility, and priority.
3. The CCFH shall agree whether a proposal for new work and/or revision of an existing standard is accepted, to be submitted for revision, or denied. If accepted: a) the priority of the new work will be established using the criteria and procedures outlined below, taking into account the ‘Criteria for the Establishment of Work Priorities’³; and b) a project document⁴ will be developed and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work.

Guidelines for Considering New Work

As specified in the Codex *Procedural Manual*, work undertaken by the Codex Committee on Food Hygiene 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*. As a means of assisting it in meeting these goals, the Committee will consider the following criteria as a means to accept and prioritize proposals for new work. A decision tool for accepting and prioritizing new work is provided in Annex I.

1. The proposal for new work should address a food hygiene issue of public health significance:
 - that is known or emerging;
 - that impacts on international trade;
 - is of interest to a [substantial] number of members; and
 - for which there is reason to believe that sufficient scientific knowledge or data are available to provide or obtain scientifically sound guidance.
2. The proposal for new work may be needed to:
 - 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).

² Definition of a risk profile is “the description of the food safety problem and its context” (Codex *Procedural Manual*, 14th Edition, p. 46). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

³ Codex *Procedural Manual*, 14th Edition, p. 67.

⁴ The elements of a project document are described in the Codex *Procedural Manual*, 14th Edition, p. 20.

Process for Prioritization of Work

The Committee will annually review, evaluate and prioritize its work. This will be carried out by the Committee through an [*Ad hoc*] “Working Group for the Establishment of CCFH Work Priorities.” The purpose of the working group is to review the proposals for completeness, consider the priority of the proposed work compared to pre-established priorities, and make a recommendation to the Committee of whether the new items should be included, delayed, or returned for additional information. The recommendation will be considered by the Committee during the acceptance of the agenda phase of the meeting session. The recommendations will present a proposed prioritization of potential new work that meet the criteria specified above in the section entitled “Guidelines for Considering New Work.”

The total resource capacity available to CCFH will dictate the total workload that could be undertaken by CCFH at any one time. A higher priority should be given to work needed to control an urgent public health hazard.

The [*Ad hoc*] “Working Group for the Establishment of CCFH Work Priorities” will also assess and provide recommendations to CCFH on the need for cross-committee interactions (see below).

If the proposed new work will benefit from the acquisition of additional expert scientific advice such as an international risk assessment, the need for FAO/WHO (e.g., JEMRA, *ad hoc* expert consultations) to be involved in the process should also be considered in prioritizing work.

Process for Commencement of New Work within CCFH

1. 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”*.
2. 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
3. As necessary and appropriate, CCFH work will request a risk assessment⁶ or other expert scientific advice from FAO/WHO using the procedure outlined below.

Acquiring Scientific Advice

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 sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations, etc.). 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*⁶.

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

1. Sufficient scientific knowledge and data to conduct the needed risk assessment are available. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)
2. 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.
3. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

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*, 14th edition, pp. 101-107.

If the Committee decides to request that a microbiological risk assessment 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 risk assessment, any time constraints facing the Committee that could impact the risk assessment, and 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 undertaken⁷. FAO/WHO will evaluate the request according to their criteria (as communicated to the CAC) and subsequently inform the Committee of its agreement to carry out such work together with a scope of work to be undertaken. 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).

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

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 groups to provide guidance on the appropriate interpretation of the risk assessment.

Unless jointly agreed upon otherwise, 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

[Members of the Working Group raised concerns that the described process is in conflict with the formal procedures associated with CAC. Concerns were raised about the transparency of the proposed process for cross-committee interactions and the procedures relative to establishing representatives from other committees on CCFH working groups.]

In many instances, the work of the Codex Committee is interconnected with the work of other Codex committees and task forces. In such instances, it may be appropriate for cross-committee interaction to occur that is more extensive than that which would occur under the standing agenda item relating to “matters referred by the Codex Alimentarius Commission and/or Other Codex Committees to the Food Hygiene.” In such situations, the following approaches may be used.

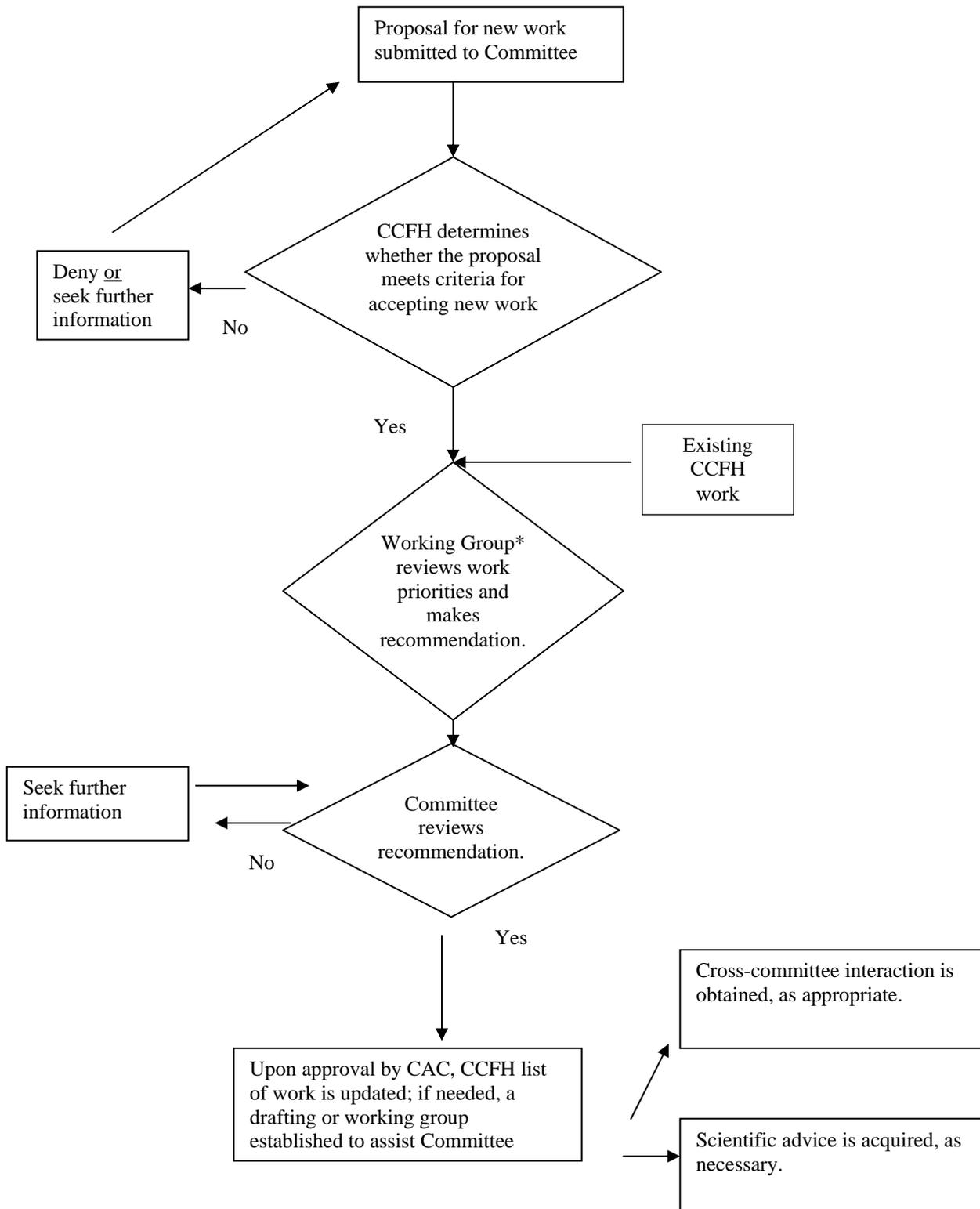
- The Chair of CCFH will regularly discuss with the Chairs of other appropriate committees for the purpose of identifying: (1) potential work that should be undertaken by CCFH, and (2) work currently underway or planned by other committees that will require or benefit from consideration by CCFH.

Once a proposal for new work and/or revision of existing standards has been approved by CCFH and CAC, the lead country for the projects’ working group should, with the assistance of the CCFH Chair, establish the needed cross-committee interaction(s). This will typically be communicated in writing to the Chair of the appropriate Codex committee(s), through the Codex secretariat. The CCFH shall clearly outline the problems and the questions that the other committee should answer.

- As appropriate, when establishing working groups on items for which a cross-committee interaction has been identified, an invitation will be made to include representatives of that committee on the CCFH working group. CCFH will specify what is expected and identify the need for persons with experience of related matters and of matters discussed in other committees.
- As appropriate, the Chair of CCFH and the Chair(s) of the other appropriate committee(s), or their designated representatives, will informally extend an invitation to the Session.

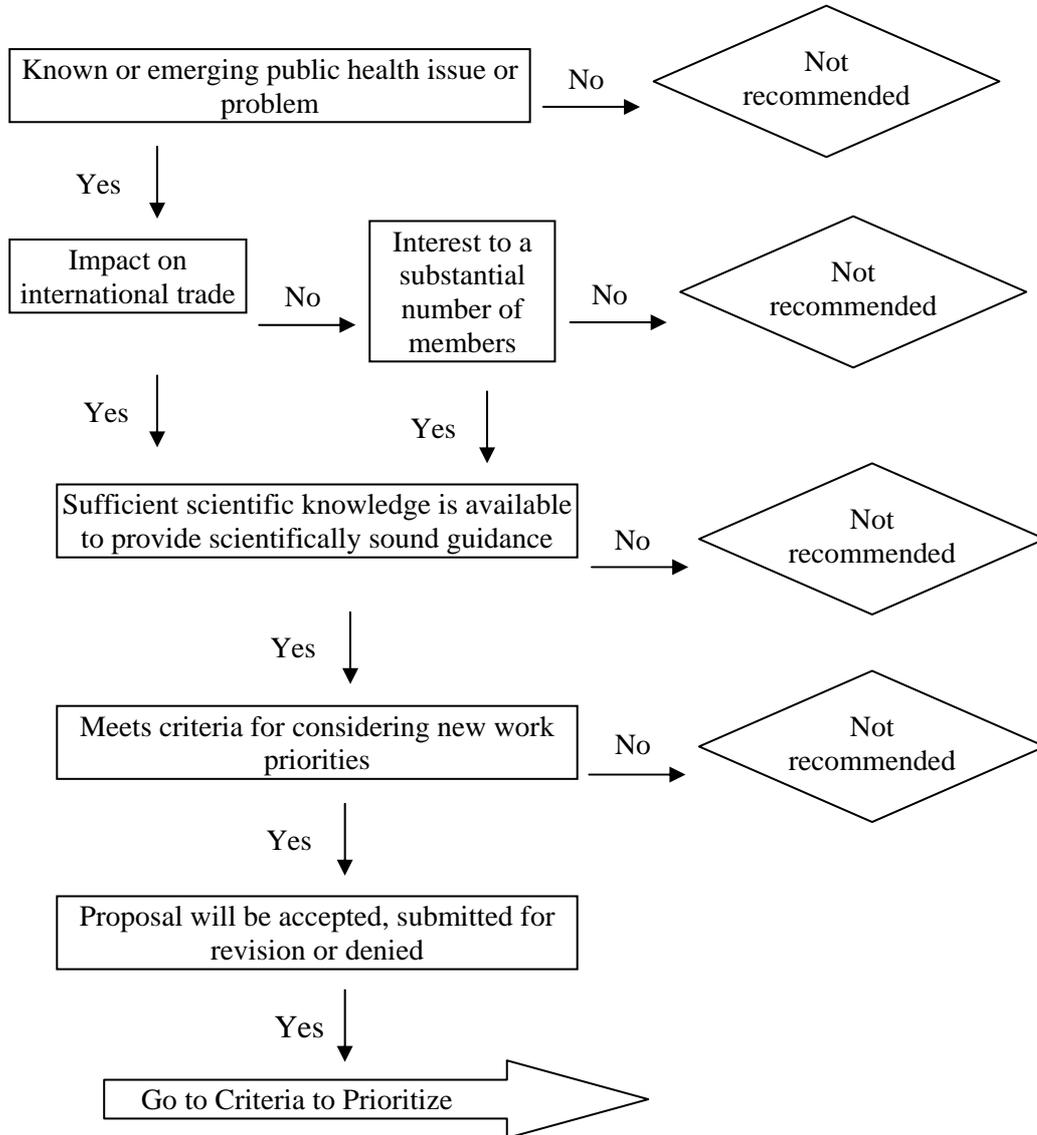
⁷ Codex *Procedural Manual*, 14th Edition, p. 46 (definition of risk assessment policy) and pp. 102-104 (working principles relating to risk assessment policy).

PROCESS OF ACCEPTING AND PRIORITIZING OF NEW AND EXISTING WORK

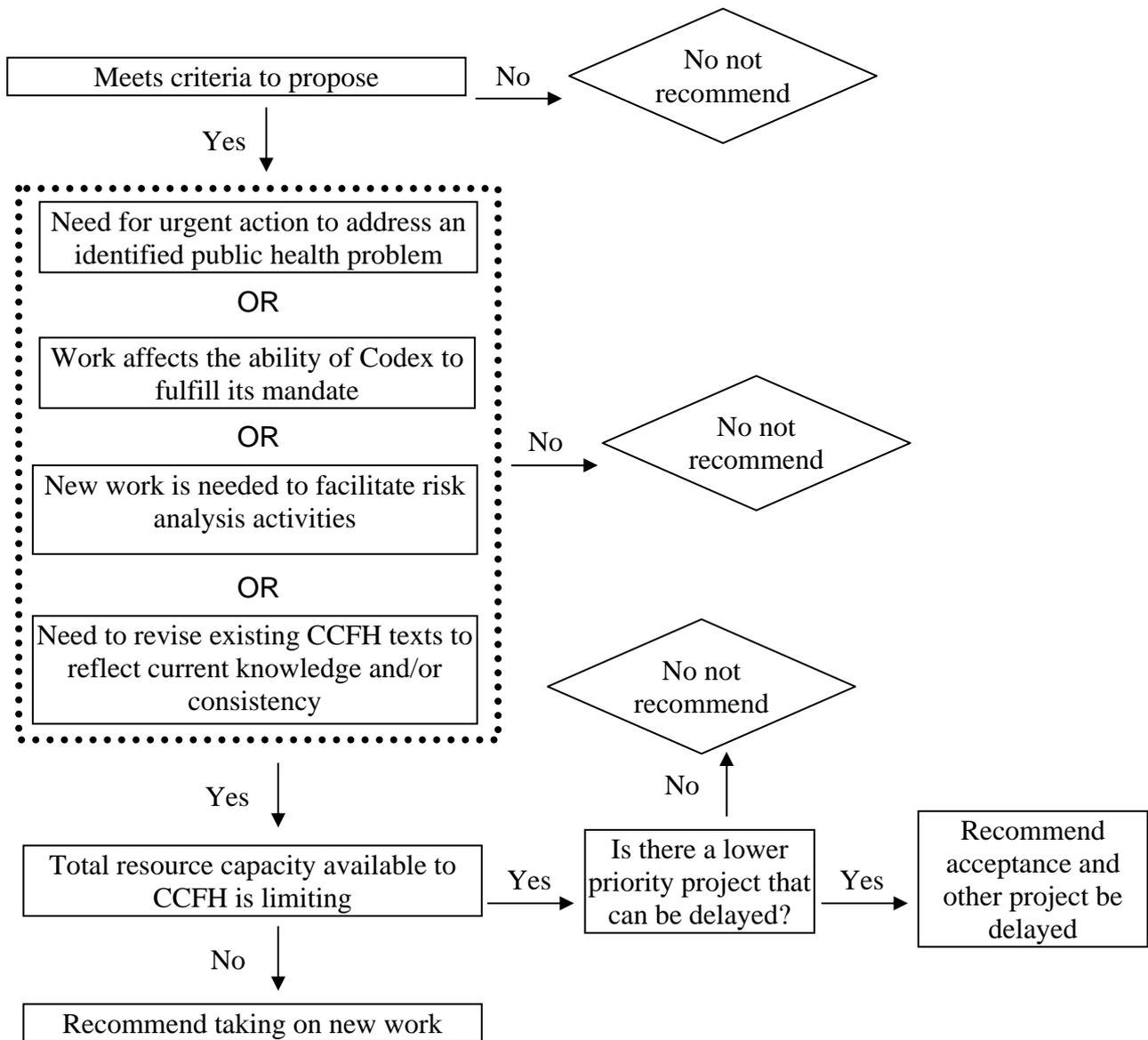


* [Ad hoc] Working Group for the Establishment of CCFH Work Priorities

**Decision Tree to Assist with
Reviewing New Work Proposals**



**Decision Tree to Assist with
Prioritization of New Work**



Annex II

ITERATIVE PROCESS BETWEEN THE CODEX COMMITTEE ON FOOD HYGIENE AND THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESMENT (JEMRA) FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESMENT

[Members of the Working Group noted that there is no established Codex procedure for CCFH to seek outside advice. It was recommended that revisions to the process described here take into consideration the results of the report of the 27-29 January 2004 Joint FAO/WHO workshop, "Provision of Scientific Advice to Codex and Member Countries."]

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 understood and addressed appropriately. 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 communication. 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.