

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
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Agenda Item 2

CX/GP 10/26/2

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-sixth Session

Paris, France, 12 – 16 April 2010

### MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES <sup>1</sup>

#### I. MATTERS ARISING/REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION (CAC32)

##### A. Items for Information

Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses

Proposed Amendment to the Working Instructions for the Implementation of the Criteria Approach in Codex

Consequential Amendment to the General Criteria for the Selection of Methods of Analysis (terminology)

The Commission adopted the proposals<sup>2</sup>.

Amendment to the Guidelines to Chairpersons of Codex Committees and ad hoc Intergovernmental Task Forces

The Commission adopted the proposal as amended.<sup>3</sup>

Proposed inclusion of an information footnote to the fourth paragraph of the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account indicating that the Acceptance Procedure was abolished in 2005

Several delegations expressed the view that the use of the term “acceptance” in the *Statements of Principle* was not intended as referring to the Acceptance Procedure abolished in 2005 and therefore did not support the insertion of a footnote referring to the abolition of that Procedure. The Commission therefore agreed to retain the text of the *Statements of Principles* unchanged.<sup>4</sup>

<sup>1</sup> This document contains: **Part I:** Matters arising/referred from the 32<sup>nd</sup> Session of the Codex Alimentarius Commission either of specific interest to the Committee for information (A) or for action (B). **Part II:** Matters referred from other Codex Committees and Task Forces that require specific action by the Committee. The Codex Secretariat will report verbally on matters of horizontal nature as appropriate to the discussion of the Committee.

<sup>2</sup> ALINORM 09/32/REP, paras. 16-17

<sup>3</sup> ALINORM 09/32/REP, paras. 18-19

<sup>4</sup> ALINORM 09/32/REP, para 21

Procedure for Standards and Related Texts Held at Step 8<sup>5</sup>

Noting that occasionally a number of texts had been retained at Step 8, the Chairperson proposed and the Commission agreed to consider that an electronic working group, to be chaired by the Netherlands, prepare a discussion paper for consideration by the Committee on General Principles to examine the factors that cause such decisions and how to address these situations. Some delegations asked for clarification on the purpose of this paper and noted that work was already ongoing on consensus and that there was a need to look at mechanisms that would help solving these situations on a case by case basis. It was further noted that any proposal should not reopen discussion on matters already included in the Procedural Manual, particularly the *Statements of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors Are Taken into Account*. The Commission noted a proposal for the terms of reference of the electronic working group to which some delegations objected on the grounds that it was ambiguous and it was difficult to understand the relation with the decision making mechanism. In view of the absence of a suitable alternative proposal, the Commission agreed not to continue discussion on this matter at this session. The Chairperson noted that the matter would be brought to the attention of the Committee on General Principles.

**B. Items for Action**

Proposed Draft Revised Code of Ethics for International Trade in Foods

The Commission adopted the Proposed Draft Revised Code of Ethics at Step 5<sup>6</sup>. The Commission emphasized however that this meant that the general structure of the draft had well advanced and only specific proposals on the text should be made and no general debate on the scope reopened. The Commission also emphasized the need to finalize this work within the next session of the CCGP. To be discussed at step 7 under Agenda Item 3.

Proposal from Malaysia to amend the section on consensus in the Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces

The Commission decided to ask the Secretariat to issue a circular letter to all members of the Commission on the Malaysian proposal, soliciting comments which would be compiled and forwarded to the CCGP for further deliberation<sup>7</sup>. To be discussed under Agenda Item 4.

Definition for the term “competent authority”

The Commission requested the Committee to look into the merit of developing a general definition for “competent authority” for inclusion in the Procedural Manual<sup>8</sup>. To be discussed under Agenda Item 6. See also the contribution from CCFICS in II.2. in this document.

Proposed Amendment to the Terms of Reference of the Committee on General Principles

The Commission did not adopt the proposal and agreed to request the Committee on General Principles to review its terms of reference<sup>9</sup>. To be discussed under Agenda Item 7.

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<sup>5</sup> ALINORM 09/32/REP, para 80

<sup>6</sup> ALINORM 09/32/REP, paras 37-41, CX/GP 10/26/3

<sup>7</sup> ALINORM 09/32/REP, para 217, CX/GP 10/26/4

<sup>8</sup> ALINORM 09/32/REP, para 105, CX/GP 10/26/6

<sup>9</sup> ALINORM 09/32/REP, para 20, CX/GP 10/26/7

Discussion paper on co-hosting of Codex sessions

The Commission agreed to ask the Codex Secretariat to prepare a discussion on measures to expedite the formal processes for co-hosting of Codex sessions<sup>10</sup>. To be discussed under Agenda Item 9.

Timely and simultaneous distribution of documents/ length and content of reports

The Commission agreed that Chile supported by other countries would prepare a discussion paper including recommendations on ways to approach the timely and simultaneous distribution of documents and the length and content of reports taking into account concerns raised at the present Session and those from the FAO/WHO Coordinating Committee for Latin America and the Caribbean, for consideration by the next session of the CCGP<sup>11</sup>. To be discussed under Agenda Item 10.

## **II. MATTERS REFERRED BY OTHER COMMITTEES**

### **1. Committee on Food Hygiene (CCFH)<sup>12</sup>**

The Committee noted that some inconsistencies might exist between the CCFH Risk Analysis Principles and Procedures and the *Annex on the Process by which the Codex Committee on Food Hygiene will undertake its work* and agreed to ask the CCGP to take care of these inconsistencies while reviewing these texts. The Committee agreed to forward the Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene to the 33<sup>rd</sup> Session of the Commission for adoption and subsequent inclusion in the Codex Alimentarius Procedural Manual.

### **2. Committee on Food Import and Export Inspection and Certification Systems (CCFICS)<sup>13</sup>**

The Committee noted the discussion at the 62<sup>nd</sup> Session of the Executive Committee concerning the inconsistent use of the term “competent authority” and the decision of the 32<sup>nd</sup> Session of the Commission to request the Committee on General Principles (CCGP) to look into the merit of developing a general definition for “competent authority” for inclusion in the Procedural Manual<sup>14</sup>. The Committee agreed to contribute the following points to the discussion in CCGP:

- The term “competent authority” is highly relevant to the work of CCFICS as is extensively used in 8 of the 9 texts developed by CCFICS;
- The Committee has considered defining the term at previous sessions but has concluded that the term was self-explanatory<sup>15</sup>;
- The term is defined through its use in CCFICS texts and, therefore, a general definition would impact on each of these texts; and
- The term is used by many governments and a general definition should not exclude any of these uses.

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<sup>10</sup> ALINORM 09/32/REP, para 157-168, CX/GP 10/26/9

<sup>11</sup> ALINORM 09/32/REP, para 194, CX/GP 10/26/10

<sup>12</sup> ALINORM 10/33/13, paras. 139-150 and Appendix VII (reprinted in the Appendix to this document)

<sup>13</sup> ALINORM 10/33/30, para 6

<sup>14</sup> ALINORM 10/32/REP, para. 105

<sup>15</sup> ALINORM 01/30A, para. 14

## Appendix

**PROPOSED DRAFT RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY  
THE CODEX COMMITTEE ON FOOD HYGIENE<sup>16</sup>****(For inclusion in Section VI of the Procedural Manual)****I. SCOPE**

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

**II. PRELIMINARY RISK MANAGEMENT ACTIVITIES**

2. The CCFH arranges to develop a risk profile for bringing forward newly proposed work. The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential microbiological risk management (MRM) options that have been identified by CCFH, if any, and the food safety policy context that will influence further possible actions. Scientific data may be commissioned from a range of sources so as to support a continuous science and risk based approach.
3. Members, who wish to make a request for inclusion of new item in the priority list of future work of CCFH, should prepare a project document in accordance with Part 2-1 of the Elaboration Procedure (Codex Procedural Manual) and provide a preliminary risk profile, based on the template in Annex 1 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007). CCFH identifies the priority of all the new topics, submitted for its consideration, based on the *Criteria for the Establishment of Work Priorities* (Codex Procedural Manual). The CCFH may also identify areas on which inputs from JEMRA are needed and make an appropriate request to JEMRA. Further details are provided in the Annex.
4. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessments and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.
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.

**III. RISK ASSESSMENT**

5. CCFH commissions JEMRA, through FAO/WHO, as the body primarily responsible for performing international risk assessments upon which CCFH and the Codex Alimentarius Commission (CAC) will base MRM options. For matters, which cannot be addressed by JEMRA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.
6. FAO/WHO will ensure that the selection of experts and other procedures follow the principles and procedures in the *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition* and in accordance with the *Principles and Guidelines for the Conduct of*

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<sup>16</sup> Reprinted Appendix VII of ALINORM 10/33/13.

*Microbiological Risk Assessment* (CAC/GL 30-1999).

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

#### **IV. RISK MANAGEMENT**

8. The MRM options recommended by the CCFH to the CAC should be based on the policies stated in the following paragraphs and shall take into account all relevant assumptions and uncertainties described by JEMRA.
9. Elaboration of 'Guidelines' or 'Codes of Hygienic Practices' could include Microbiological Criteria (MC) and/or provide enabling tools/procedures for countries to apply other MRM metrics (e.g., FSO, PO, PC), as outlined in Annex II of the MRM document (CAC/GL 63-2007), to address a food safety risk.
10. In cases where JEMRA has performed a risk assessment and CCFH or the CAC determines that additional scientific guidance is necessary, CCFH or CAC may make a specific request to JEMRA to provide further scientific guidance necessary for deciding on an appropriate MRM option.
11. CCFH decides, on a case-by-case basis, the need to elaborate 'Guidelines' or 'Codes of Hygienic Practices', and/or to establish an 'MC', or provide enabling tools/procedures for countries to apply other MRM metrics. In most cases, elaboration of a 'Guideline' or a 'Code of Hygienic Practices' is the preferred MRM option and should address food safety concerns in a diverse array of situations that prevail globally. It also provides the necessary flexibility to address/manage the risk to an acceptable level in the most efficient and appropriate manner. Also, for certain products that are intended for consumption by sensitive sub-populations (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immuno-compromised persons, etc.), it may be necessary for the CCFH to establish MCs and/or provide enabling tools/procedures for countries to apply other MRM metrics.
12. Where appropriate, other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, may also be considered by the CCFH, as described in the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Codex Procedural Manual). When establishing MRM options, CCFH shall clearly state when it applies any considerations based on other legitimate factors and specify its reasons for doing so.
13. Wherever possible, CCFH should consider establishing MCs for those pathogen – food combinations for which JEMRA is able to provide a quantitative microbiological risk assessment.

Recommendations by CCFH should be based on the outcomes of the risk assessment taking into account differences in regional and national food consumption patterns and dietary exposure. The applicable guidance provided in the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) shall be utilized by the CCFH for establishment of MCs.

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

## **V. RISK COMMUNICATION**

15. In accordance with the *Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCFH, in co-operation with JEMRA, should ensure that the risk analysis process is fully transparent and thoroughly documented and that the results are made available to the members in a timely manner. The CCFH recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities. To this end, the CCFH and JEMRA should utilise the guidance on interaction provided in paras 18 through 23.
16. 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.

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

18. The CCFH recognizes that an iterative process between risk managers and risk assessors is essential for adequate undertaking of any microbiological risk assessment and development of MRM options. In particular, a dialogue between the CCFH and JEMRA is desirable to thoroughly assess the feasibility of the risk assessment, to assure that the risk assessment policy is clear, and to ensure that the risk management questions posed by the CCFH are appropriate.
17. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees, other FAO/WHO expert consultations and/or other specialized international scientific bodies, these should be included into the iterative process.
19. It is essential that communications between CCFH and JEMRA are timely and effective.
20. CCFH is likely to receive questions from JEMRA relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the MRM options to be considered and key assumptions to be made regarding the risk assessment. Likewise, the CCFH may pose questions to JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop the MRM options.
22. CCFH may recommend to the CAC to discontinue or modify work on an MRM option if the iterative process demonstrates that: (a) completion of an adequate risk assessment is not feasible; or (b) it is not possible to provide appropriate MRM options.
23. 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.

## 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.
  - v. 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’<sup>1</sup>. 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.

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<sup>1</sup> Codex Alimentarius Commission, *Procedural Manual*

- 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 document<sup>2</sup>, 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 Profile<sup>3</sup>, 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*<sup>4</sup>.

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:

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<sup>2</sup> The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*,

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

<sup>4</sup> Codex Alimentarius Commission, *Procedural Manual*.



- 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.

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 30-1999).